

Reed Smith Health Care Reform Review

The Patient Protection and Affordable Care Act, as Amended by the Reconciliation Act:

Focus on Health Care Providers and Medical Product Manufacturer Impact

April 2010

ReedSmith

The business of relationships.™

Table of Contents

Introduction..... 1

Title I—Quality, Affordable Health Care for All Americans 3

Title II—Role of Public Programs..... 7

Subtitle A—Improved Access to Medicaid..... 7

Subtitle B—Enhanced Support for the Children's Health Insurance Program (CHIP) 9

Subtitle C—Medicaid and CHIP Enrollment Simplification..... 10

Subtitle D—Improvements to Medicaid Services 11

Subtitle E—New Options for States to Provide Long-Term Services and Supports 12

Subtitle F—Medicaid Prescription Drug Coverage 13

Subtitle G—Medicaid Disproportionate Share Hospital (DSH) Payments..... 17

Subtitle H—Improved Coordination for Dual Eligible Beneficiaries.... 18

Subtitle I—Improving the Quality of Medicaid for Patients and Providers 19

Subtitle J—Improvements to the Medicaid and CHIP Payment and Access Commission (MACPAC) 22

Subtitle K—Protections for American Indians and Alaska Natives..... 23

Subtitle L—Maternal and Child Health Services 23

Title III—Improving the Quality and Efficiency of Health Care 24

Subtitle A—Transforming the Health Care Delivery System 24

Part I—Linking Payment to Quality Outcomes under the Medicare Program..... 24

Part II—National Strategy to Improve Health Care Quality 33

Part III—Encouraging Development of New Patient Care Models .. 35

NEW YORK
 LONDON
 HONG KONG
 CHICAGO
 WASHINGTON, D.C.
 BEIJING
 PARIS
 LOS ANGELES
 SAN FRANCISCO
 PHILADELPHIA
 PITTSBURGH
 OAKLAND
 MUNICH
 ABU DHABI
 PRINCETON
 N. VIRGINIA
 WILMINGTON
 SILICON VALLEY
 DUBAI
 CENTURY CITY
 RICHMOND
 GREECE

Subtitle B—Improving Medicare for Patients and Providers 43

 Part I—Ensuring Beneficiary Access to Physician Care and Other Services..... 43

 Part II—Rural Protections 45

 Part III—Improving Payment Accuracy 47

Subtitle C—Provisions Relating to Part C..... 54

Subtitle D—Medicare Part D Improvements for Prescription Drug Plans and MA–PD Plans..... 57

Subtitle E—Ensuring Medicare Sustainability 65

Subtitle F—Health Care Quality Improvements..... 70

Subtitle G—Protecting and Improving Guaranteed Medicare Benefits 74

Title IV—Prevention of Chronic Disease and Improving Public Health.. 75

 Subtitle A—Modernizing Disease Prevention and Public Health Systems..... 75

 Subtitle B—Increasing Access to Clinical Preventive Services 75

 Subtitle C—Creating Healthier Communities..... 77

 Subtitle D—Support for Prevention and Public Health Innovation 78

 Subtitle E—Miscellaneous Provisions 79

Title V—Health Care Workforce 82

 Subtitle B—Innovations in the Health Care Workforce 82

 Subtitle C—Increasing the Supply of the Health Care Workforce 83

 Subtitle D—Enhancing Health Care Workforce Education and Training 84

 Subtitle E—Supporting the Existing Health Care Workforce 86

 Subtitle F—Strengthening Primary Care and Other Workforce Improvements 87

 Subtitle G—Improving Access to Health Care Services 88

Title VI—Transparency and Program Integrity 90

 Subtitle A—Physician Ownership and Other Transparency 90

NEW YORK
LONDON
HONG KONG
CHICAGO
WASHINGTON, D.C.
BEIJING
PARIS
LOS ANGELES
SAN FRANCISCO
PHILADELPHIA
PITTSBURGH
OAKLAND
MUNICH
ABU DHABI
PRINCETON
N. VIRGINIA
WILMINGTON
SILICON VALLEY
DUBAI
CENTURY CITY
RICHMOND
GREECE

Subtitle B—Nursing Home Transparency and Improvement 96

 Part I—Improving Transparency of Information..... 96

 Part II—Targeting Enforcement 98

 Part III—Improving Staff Training..... 99

Subtitle C—Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long-Term Care Facilities and Providers..... 100

Subtitle D—Patient-Centered Outcomes Research..... 100

Subtitle E—Medicare, Medicaid, and CHIP Program Integrity Provisions 101

Subtitle F—Additional Medicaid Program Integrity Provisions 108

Subtitle G—Additional Program Integrity Provisions 109

Subtitle H—Elder Justice Act (EJA) 111

Subtitle I—Sense of the Senate Regarding Medical Malpractice 112

Title VII—Improving Access to Innovative Medical Therapies 114

 Subtitle A—Biologics Price Competition and Innovation 114

 Subtitle B—More Affordable Medicines for Children and Underserved Communities..... 118

Title VIII—CLASS Act 120

Title IX—Revenue Provisions 121

 Subtitle A—Revenue Offset Provisions..... 121

Conclusion 124

About Reed Smith 124

Contributors 125

Appendix A – Glossary of Terms 126

NEW YORK
LONDON
HONG KONG
CHICAGO
WASHINGTON, D.C.
BEIJING
PARIS
LOS ANGELES
SAN FRANCISCO
PHILADELPHIA
PITTSBURGH
OAKLAND
MUNICH
ABU DHABI
PRINCETON
N. VIRGINIA
WILMINGTON
SILICON VALLEY
DUBAI
CENTURY CITY
RICHMOND
GREECE

Introduction

On March 23, 2010, President Obama signed into law H.R. 3590, the Patient Protection and Affordable Care Act (PPACA),¹ a sweeping measure designed to expand access to health insurance (including subsidies, mandates, and market reforms); reduce health care spending (particularly in the Medicare program); expand federal fraud and abuse authorities and transparency requirements; impose new taxes and fees on health industry sectors; and institute a variety of other health policy reforms.

The President signed a second, related bill into law March 30, 2010 -- H.R. 4872, the Health Care and Education Reconciliation Act of 2010 (Reconciliation Act)² – which includes a series of "fixes" to the PPACA. The Reconciliation Act makes substantive changes to a number of the PPACA's health-related policies, including insurance coverage provisions, revisions to Medicare prescription drug coverage, Medicare Advantage and fee-for-service payments, Stark Law self-referral policy, and Medicaid matching payments, among many others.

The PPACA, as amended by the Reconciliation Act, is dramatic and far-reaching. Perhaps the most significant result of the PPACA will be the expansion of health insurance coverage to approximately 32 million Americans who currently receive no health benefits, principally through the expansion of the Medicaid program and the imposition of health insurance mandates on employers and individuals. However, within the 2407 pages of the PPACA and the additional 148 pages of the Reconciliation Act are numerous provisions that will have a direct and material impact on nearly every component of the health care delivery and financing systems in the United States, including health insurers, health care providers, and manufacturers of pharmaceuticals and medical devices, as well as employers, taxpayers, and patients.

While dramatic and far-reaching, the PPACA leaves intact most of the existing infrastructure through which health care is delivered and paid. Most Americans will continue to receive health benefits through commercial insurance products offered by their employers (although new insurance exchanges are designed to expand access to insurance for individuals outside of group health markets). Most health care providers will continue to be reimbursed under the current general payment structures (that is, through private insurers or government health plans). Thus, the existing fragmented delivery and financing system, though affected by health reform, will not immediately be swept away by this legislation.

Although the PPACA did not usher in a transformation in the American health care system, it does signal the beginning steps toward potentially fundamental changes to the existing health care delivery infrastructure. For example, the development of programs for Medicare payments

¹ Public Law No. 111-148. The text of the PPACA as approved is available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590eas.txt.pdf.

² Public Law No: 111-152. The text of the Reconciliation Act is available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h4872enr.txt.pdf.

to accountable care organizations and demonstration programs for bundled payments, gainsharing and home-based primary care, could lead to more prevalent vertical integration of the delivery system. Further, by empowering a new Independent Payment Advisory Board to recommend changes to the Medicare program to limit its spending growth – and providing that its recommendations would go into effect automatically unless Congress votes to block them – other significant (but heretofore politically difficult) payment changes could emerge that would affect the organization of the delivery system. Likewise, the PPACA's expansion of value-based purchasing programs and comparative effectiveness-research signal a continued focus on tying Medicare payment to quality outcomes.

Thus, in evaluating the impact of the PPACA and Reconciliation Act, participants in the health care industry should consider the legislation on two levels. To be sure, they should be mindful of the immediate and direct effects on their activities. In addition, however, they should consider the potential for significant transformational changes encouraged by the legislation that could, over time, also impact their businesses.

A note on our analysis.

The sweeping health reform legislation is comprised of two separate laws, the PPACA and the Reconciliation Act. The PPACA – which is the primary health reform document -- is an exceptionally lengthy and complex law, with some provisions adopted in one section of the PPACA amended again in a later section of the same law. Unless otherwise noted, section numbers in our Alert refer to the PPACA. Moreover, the PPACA must be read together with the amendments adopted in the separate Reconciliation Act. For the reader's convenience, we typically discuss the Reconciliation Act provisions with the associated PPACA provisions. We have also appended to this memorandum a glossary of the many acronyms appearing in this analysis and throughout the legislation.

In addition, this Alert, while lengthy, concentrates on those provisions we believe are of most interest to health care providers and medical device and pharmaceutical manufacturers. While we include a brief discussion of the private insurance coverage reforms and discuss the pharmaceutical and device manufacturer taxes in the bill, a detailed examination of the PPACA's insurance and tax provisions is beyond the scope of this analysis, as is a comprehensive discussion of each of the provisions in the thousands of pages of text.³ We would be pleased, however, to provide analyses targeted at specific industry sectors, or to assist you in developing plans to respond to implementation of the new health reform legislation.

³ Reed Smith's Tax, Benefits & Welfare Planning Group has released a summary of provisions of the legislation affecting health plans at <http://reedsmithupdate.com/ve/ZZS31906392JkK83b72v>, as has the State Tax Group <http://reedsmithupdate.com/ve/ZZN613093X71uDYOT80>. Congressional leaders also have posted background information, including an implementation timeline, at http://dpc.senate.gov/dpcdoc-sen_health_care_bill.cfm.

Title I—Quality, Affordable Health Care for All Americans

Title I of the PPACA, as amended by the Reconciliation Act, contains extensive provisions designed to improve access to affordable health insurance coverage through group health plan and insurance market reforms, developing insurance exchanges, providing premium subsidies to certain individuals and businesses, and establishing individual and employer insurance mandates. The provisions are briefly noted below, and they are discussed in greater detail in Reed Smith's Benefits Alert.⁴ Also below is a more specific discussion of new False Claims Act (FCA) authority related to payments made through new Health Benefits Exchanges (the Exchanges).

General Overview of Title I

- **Group Health Plan and Insurance Market Reforms.** The PPACA prevents certain practices by group health plans, including self-insured plans, and insurers. Among other things, the PPACA: bans lifetime and annual limits on the dollar value of essential benefits; limits rescissions of a health care policy except in cases of fraud; requires coverage of certain preventive services; bans pre-existing condition exclusions; establishes nondiscrimination rules and other participant protections; imposes requirements regarding summaries of benefits, quality reporting, and appeals processes; requires plans to account for costs; and enhances state and federal oversight of plans. The PPACA also includes reforms to the general health insurance market, including, among others: a ban on pre-existing condition exclusions; restrictions on variations in premiums; annual limits on cost-sharing and deductibles; a ban on discrimination based on health status; protections against discrimination with respect to participation by health care providers (but insurers are not required to contract with all willing health care providers); and provisions related to participation in approved clinical trials and wellness programs. The PPACA also requires plans in the individual and small-group markets to cover the "essential health benefits package," as defined in the PPACA.
- **Expanding Affordable Coverage.** The PPACA provides for a temporary high-risk health insurance pool program, a temporary reinsurance program for early retirees; expanded access to insurance information; and amendments to the Health Insurance Portability and Accountability Act (HIPAA) and Social Security Act (SSA) with respect to standards and operating rules for financial and administrative transactions.
- **Preservation of Existing Coverage.** The PPACA does not require an individual to terminate coverage under a group health plan or health insurance coverage in which he or she is enrolled on the date of enactment. In addition, plans operating as of enactment are grandfathered and excused from complying with many of the PPACA's requirements.

⁴ See <http://reedsmithupdate.com/ve/ZZS31906392JkK83b72y>. Note that effective dates of these provisions vary.

- **Health Care Exchanges.** To assist individuals who do not have health plan coverage, the Secretary of Health and Human Services (Secretary) must provide grants to establish American Health Benefit Exchanges. By January 1, 2014, each state is required to establish an Exchange, generally defined as a governmental agency or nonprofit entity established to facilitate the purchase of Qualified Health Plans by eligible individuals and employers. The PPACA defines a "Qualified Health Plan" as a plan that (a) is certified by the Exchange through which it is offered; (b) provides "Essential Health Benefits," as defined by the PPACA; and, (c) is offered by a health insurance issuer that satisfies various requirements. The PPACA also permits the establishment of member-run, nonprofit Consumer Operated and Oriented Plans (CO-OPs) to provide Qualified Health Plans, and states may establish additional plans outside of the Exchange.
- **Assistance for Insurers, Individuals and Small Businesses.** The PPACA provides assistance, in the form of a reinsurance program and risk corridors, for insurers who cover high-risk individuals. It also provides a premium assistance credit, in the form of a refundable tax credit based on income, for low-income taxpayers enrolled in private health insurance through an Exchange, along with reduced cost-sharing for certain low-income individuals enrolling in qualified health plans. In addition, small businesses (those with fewer employees with average wages of less than \$50,000) that purchase health insurance for their employees can qualify for a tax credit.
- **Individual Coverage Mandate.** Beginning January 1, 2014, individuals will be required to maintain minimum essential coverage or pay a penalty to the federal government (with numerous exceptions). The penalty will be determined based on a formula considering average premium costs for certain exchange plans, household income, certain flat dollar amounts, and the number of applicable individuals who do not have coverage.
- **Employer Mandates.** Effective January 1, 2014, the PPACA imposes new requirements on employers, including those who do not currently provide health care coverage. Specifically, large employers (those with more than 50 full-time equivalent employees) will be subject to monthly assessments if the employer's group health plans do not satisfy certain requirements. Large employers who do not offer employees and their dependents a plan providing minimum essential coverage, but who have at least one employee who has enrolled in a Qualified Health Plan and who are receiving premium assistance credits or cost-sharing reductions, will be required to pay an annual fee (generally \$2,000, indexed for inflation, multiplied by the number of employees over 30 employed by the employer). In addition, a group health plan that has employees qualify for a premium assistance credit or cost-sharing reduction will be required to pay a fee equal to the lesser of (i) \$3,000 for each employee or (ii) \$2,000 for each full-time equivalent employee in excess of 30 employees. Moreover, employers with 200 or more full-time equivalent employees that provide a group health plan will be required to automatically enroll all new employees

and continue the enrollment of current employees in a health benefit plan offered by the employer. Employers that offer minimum essential coverage to their employees also will be required to offer certain employees the option of either enrolling in the employer's plan or receiving a tax-free voucher from the employer.

- **Tax Provisions.** The PPACA also includes numerous changes to the Internal Revenue Code that will impact the taxation of health benefits, including a tax on high-cost, employer-sponsored health coverage, otherwise known as Cadillac Plans.

Health Benefit Exchanges: Financial Integrity and the False Claims Act (Sec. 1313, 10104)

This section applies the federal FCA to payments made through Health Benefits Exchanges if the payments include any federal funds.

As amended by section 10104, the legislation significantly changes the FCA Public Disclosure Bar. Specifically, the legislation eliminates the bar as a jurisdictional defense and expands the definition of "original source" to include individuals who provide information to the government that is "independent of and materially adds to the publicly disclosed allegations or transaction...." Courts still have the authority to dismiss cases based upon public disclosures, but only if the government does not oppose the motion. Finally, the definition of the forum for disclosure has changed: state proceedings or proceedings where the United States is not a party will no longer serve as a basis for public disclosure.

This section also requires the Government Accountability Office (GAO) to study the cost and affordability of qualified health plans offered through Exchanges.

Under the previous public disclosure provisions, a court did not have jurisdiction over a qui tam suit (brought on behalf of the federal government by a private citizen or "relator") if the allegations and transactions upon which the suit was based had been publicly disclosed in the news media, or in a prior civil, criminal, congressional or administrative hearing, report, audit, or investigation. The relator could only avoid dismissal of her claims pursuant to this public disclosure bar by demonstrating that she was an "original source" of the information, which was defined as an individual with "direct and independent knowledge" of the allegations.

The amendments to the FCA severely undercut the public disclosure bar in three ways.

First, the new provisions provide the government – not the court – with the authority to determine whether an action should be dismissed on public disclosure grounds. The amendment provides that a court "shall dismiss an action or claim" if the allegations and transactions are based upon public information "unless opposed by the government." This change will likely result in protracted litigation of parasitic qui tam suits that should be dismissed on the pleadings. The government will have little incentive to concede dismissal because prolonged litigation on "public claims" – even if they are meritless – will likely force FCA defendants to settle claims, potentially creating a windfall for the government and the relator.

Second, the new provisions restrict the types of "public" information that would merit dismissal. Before the March 23, 2010, revisions, the public disclosure bar divested courts of jurisdiction over actions that were based on information that had been publicly disclosed in a criminal, civil, or administrative hearing; or a congressional, administrative, or GAO report, hearing, audit, or investigation; or in the news media. Now, however, only "federal" criminal, civil, and administrative proceedings, in which the "government or its agent is a party," will qualify as the type of disclosures that can preclude subsequent qui tam actions. The recent changes also limit the public disclosure bar's application to strictly "federal" reports, audits, and investigations, and altogether eliminate "administrative" reports, audits, and investigations as a basis for dismissal. The result of these changes is that potential relators can obtain information from state or local hearings, trials, investigations and proceedings, and turn around to use that information as the basis for a qui tam suit – despite the fact that the state material was readily available in the public domain. This revision is a preemptive strike by Congress to moot the issue of whether a state report can qualify as a public disclosure – an issue that has been briefed and argued before the U.S. Supreme Court and was awaiting a written decision in the case of *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, No. 08-304.

Third, the new law removes the previous requirement in the "original source" exception that an individual have "direct and independent knowledge" to proceed with an action despite the existence of a public disclosure. Instead, under the newly revised FCA, a relator may qualify as an "original source" if she voluntarily provided information to the government prior to the public disclosure, or if he has knowledge that is "independent of" and "materially adds" to the publicly disclosed allegations. Previously, to qualify as an original source, a relator was required to have "direct" (or first-hand, personal) knowledge of the publicly-disclosed facts supporting allegations of fraud, and this requirement served to screen out fraud allegations based on unreliable hearsay and second-hand sources. The elimination of the "direct knowledge" requirement threatens to force FCA defendants to face wholly unsupported allegations and "fishing expeditions" that are otherwise not based on any factual premise. Equally troubling, the new law does not describe the nature or quantity of information that a relator must allege to "materially add" to the publicly disclosed allegations. There is little doubt that the term "materially adds" will be the hotly contested subject of future litigation concerning the public disclosure bar, as these amendments turn long-settled interpretations of the public disclosure bar on their heads.

Title II—Role of Public Programs

Subtitle A—Improved Access to Medicaid

Medicaid Coverage for the Lowest Income Population (Sec. 2001, 10201, Reconciliation Act Sec. 1201)

In order to improve access to Medicaid, section 2001 of the PPACA establishes a new state option, beginning January 1, 2011, to provide Medicaid coverage to additional individuals in each state through an amendment to its state plan of medical assistance. Eligible individuals include those under age 65, who are not pregnant and not entitled to Medicare. The section creates a new mandatory Medicaid eligibility category for individuals with income at or below 133% of the Federal Poverty Level (FPL) beginning January 1, 2014 ("newly eligible individuals"). Furthermore, as of January 1, 2014, the mandatory Medicaid income eligibility level for children ages 6 to 19 changes from 100% FPL to 133% FPL. States have the option to provide Medicaid coverage to all individuals under the age of 65 and above 133% of FPL through a state plan amendment.

Section 2001 provides for increased federal assistance to the states. From 2014 through 2016, the federal government will pay 100% of the cost of covering the newly eligible individuals. In 2017 and 2018, states that previously did not cover the newly eligible population (non-expansion states) will receive more assistance than those states that covered at least some newly eligible individuals (expansion states). Note that a state that currently offers health benefits coverage to only parents or only non-pregnant childless adults is not considered an expansion state. Non-expansion states will receive a Federal Medical Assistance Percentage (FMAP) increase for services provided to newly eligible individuals of 34.3 and 33.3 percentage points in 2017 and 2018, respectively. Expansion states will receive 30.3 and 31.3 percentage points in 2017 and 2018, respectively. Beginning in 2019 and thereafter, all states will receive an FMAP increase of 32.3 percentage points for such services. However, from 2017 on, the FMAP may never exceed 95%. Section 1201 of the Reconciliation Act amended this provision, though, to provide federal Medicaid matching payments for the costs of services to expansion populations at the following rates in all states: 100% in 2014 through 2016; 95% in 2017; 94% in 2018; 93% in 2019; and 90% thereafter. In the case of expansion states, section 1201 reduces the state share of the costs of covering non-pregnant childless adults by 50% in 2014, 60% in 2015, 70% in 2016, 80% in 2017, and 90% in 2018. In 2019 and thereafter, expansion states will bear the same state share of the costs of covering non-pregnant childless adults as non-expansion states (e.g., 7% in 2019, 10% thereafter).

Under the terms of PPACA section 2001, newly eligible individuals will receive benchmark or benchmark-equivalent coverage consistent with the requirements of section 1937 of the SSA. Such medical assistance must be provided subject to the requirements of section 1937, without regard to whether a state otherwise has elected the option to provide medical assistance

through coverage under that section. Benchmark and benchmark-equivalent coverage is required to provide at least "essential benefits" (as defined in section 1302 of the PPACA). Prescription drugs and mental health services are added to the list of services that must be covered at actuarial equivalence.

Under section 2001, states are required to maintain the same income eligibility levels through December 31, 2013 for all adults. This "maintenance of effort" (MOE) requirement will be extended through September 30, 2019 for all children currently covered in Medicaid or CHIP. Between January 1, 2011 and January 1, 2014, a state will be exempt from the MOE requirement for optional, non-pregnant, non-disabled, adult populations whose family income is above 133% of FPL if the state certifies to the Secretary that the state is currently experiencing a budget deficit, or projects having a budget deficit in the following state fiscal year (FY).

The amendments to the Social Security Act made by section 10201 of the PPACA added provisions that extend Medicaid coverage to certain populations, limit coverage to other populations, and clarify terminology used in previous provisions of the legislation. Section 10201 makes mandatory the state option to cover former foster children in Medicaid, moves the effective date up to 2014, and limits the option to only those children who have aged out of the foster care system as of the date of enactment. Furthermore, the amendments move to April 1, 2010 the start date for the Medicaid state option to cover adults at or below 133% of FPL, and include a number of clarifications and some policy adjustments related to the Medicaid expansion to 133% of FPL. The amendments include provisions that:

- Clarify that to qualify as an expansion state, the benefit package offered to eligible individuals must include inpatient hospital services. (Sec. 10201)
- Clarify that under the definition of "newly eligible," current coverage levels are pegged to December 1, 2009. (Sec. 10201)
- Provide a limited matching rate increase to states that have already undertaken a Medicaid expansion that will not have any "newly eligible" beneficiaries. (Sec. 10201)
- Require states to share the benefit of increased federal match with political subdivisions (like counties) that contribute to the non-federal share of Medicaid costs. (Sec. 10201)
- Apply the pre-2017 matching rate to subsequent years in Nebraska (and only Nebraska). Accordingly, Nebraska would have a permanent 100% federal matching rate for the Medicaid costs of its expansion populations. However, section 1201 of the Reconciliation Act strikes this provision. (Sec. 10201, Reconciliation Act Sec. 1201)

Section 10201 of the PPACA also clarifies that new mandatory coverage of childless adults in territories is tied to current eligibility levels for parents in the territories. The section clarifies that children who cannot enroll in the CHIP because allotments are capped are deemed ineligible for CHIP and, therefore, eligible for tax credits in the Exchanges.

Additionally, the section gives Hawaii a Medicaid Disproportionate Share Hospital (DSH) allotment, scales back the reductions in federal Medicaid allotments for DSH, and clarifies the

effective date for the DSH policy. For waiver programs, the amendments increase the transparency of the Medicaid waiver development and approval processes at the state and federal levels, and also direct the comptroller general to conduct a study, within two years of enactment, as to whether implementation of provisions in the legislation would result in the establishment of a new cause of action or claim.

Income Eligibility for Non-elderly Determined Using Modified Gross Income (Sec. 2002)

Beginning January 1, 2014, states will be required to use modified gross income to determine Medicaid eligibility, the same measure used in the state exchanges. Under section 2002, income-disregards and asset tests no longer apply in Medicaid, except for long-term services and supports. Accordingly, no type of income, expense, or bloc- disregard may be applied to determine income eligibility for Medicaid. Existing Medicaid income counting rules will continue to apply for certain exempted groups, including (1) individuals that are eligible for Medicaid through another program, (2) the elderly or Social Security Disability Insurance (SSDI) program beneficiaries, (3) the medically needy, (4) enrollees in a Medicare Savings Program, and (5) the disabled.

Other Improvements to Medicaid Access (Sec. 2003-2006)

Also included in the subtitle on improving access are topics covering:

- Requiring states to offer premium assistance and wrap-around benefits to all Medicaid beneficiaries who are offered employer-sponsored insurance (ESI) if it is cost-effective to do so, based on current law requirements. (Sec. 2003)
- Permitting extended eligibility to all individuals below the age of 25 who were formerly in foster care for at least six months. (Sec. 2004)
- Increasing spending caps for the territories by 30% and the applicable FMAP by 5 percentage points (to 55%) beginning January 1, 2011, and for each fiscal year thereafter. Beginning in 2014, payments made to the territories for amounts expended for medical assistance for newly eligible individuals would not count against the spending caps. (Sec. 2005)
- Reducing projected decreases in Medicaid funding for states that have experienced major statewide disasters. (Sec. 2006)
- Rescinding funds available in the Medicaid Improvement Fund (MIF) for FYs 2014 through 2018. (Sec. 2007)

Subtitle B—Enhanced Support for the Children's Health Insurance Program (CHIP)

Under the new CHIP provisions, states are required to maintain current income eligibility levels for CHIP through September 30, 2019 (i.e., states cannot make eligibility standards more restrictive). From FYs 2014 to 2019, states will receive a 23 percentage-point increase in the CHIP match rate, subject to a cap of 100%. Children who are eligible, but who cannot enroll in CHIP because of federal allotment caps, will be eligible for tax credits in the state exchange.

Furthermore, if any child is determined to be ineligible for medical assistance under the state Medicaid plan or under a waiver of the plan as a result of the elimination of the application of an income-disregard based on expense or type of income (as added by the PPACA), the state must treat that child as a targeted low-income child under section 2110(b), and must provide child health assistance to the child under the state child health plan.

Section 10203 extends the current reauthorization period of CHIP for two years, through September 30, 2015. States will receive a 23 percentage-point increase in their federal match rates beginning FY 2016 through FY 2019. This provision also increases outreach and enrollment grants by \$40 million, makes some children of public employees eligible for CHIP, and precludes transitioning coverage from CHIP to the Exchange without certification by the Secretary. It also requires insurers in the Exchange to report to the Secretary on pediatric quality measures.

Technical Corrections (Sec. 2102)

Section 2101 makes technical corrections to provisions in the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) and the American Recovery and Reinvestment Act of 2009 (ARRA).

Subtitle C—Medicaid and CHIP Enrollment Simplification

Enrollment Simplification and Coordination with State Health Insurance Exchanges (Sec. 2201)

Section 2201 of the PPACA allows individuals to apply for and enroll in Medicaid, CHIP or the Exchange through a state-run website. The section mandates coordination between state Medicaid and CHIP programs and the Exchange for enrollment procedures to provide seamless enrollment for all programs.

Under section 2201, the states must also establish procedures for enrolling, without any further determination by the state and through the website, individuals who are identified through the Exchange as eligible for Medicaid. Individuals who are determined not to be eligible for Medicaid must be screened for enrollment in qualified health plans offered through such an Exchange and, if eligible, enrolled in such plan without having to submit additional paperwork. The state Medicaid agency and the state CHIP agency may enter into an agreement with an Exchange, under which the state Medicaid agency or state CHIP agency may determine whether a state resident is eligible for premium assistance for the purchase of a qualified health plan (and, if applicable, advance payment of such assistance under section 1412), so long as the agreement meets such conditions and requirements as the Secretary of the Treasury may prescribe to reduce administrative costs, and the likelihood of eligibility errors and disruptions in coverage. The section also requires states to ensure that a non-pregnant, non-elderly adult whose family income exceeds 100% but does not exceed 133% of the FPL, and who is Medicaid-eligible and eligible to receive premium credits for Exchange coverage, is offered an option to elect to enroll himself or herself (or the family if applicable) in an Exchange plan instead of Medicaid.

Permitting Hospitals to Make Presumptive Eligibility Determinations for All Medicaid Eligible Populations (Sec. 2202)

Section 2202 permits any hospital the option, based on preliminary information, to provide Medicaid services during a period of presumptive eligibility to members of all Medicaid eligibility categories. This section takes effect January 1, 2014, and applies to services furnished on or after that date.

Subtitle D—Improvements to Medicaid Services

Improvements to Medicaid Services (Sec. 2301-2304, 10202, 10211-10214, 10221)

Subtitle D of Title II covers a number of areas, including optional coverage for family planning services. Under section 2303, states have the option to add a new categorically needy eligibility group to Medicaid comprised of (1) non-pregnant individuals with income up to the highest level applicable to pregnant women covered under Medicaid or CHIP, and (2) individuals eligible under the standards and processes of existing section 1115 waivers that provide family planning services and supplies. The benefits under section 2303 are limited to family planning services and supplies, including related medical diagnostic and treatment services. The Reconciliation Act subsequently added the requirement that Medicaid payment rates to primary care physicians for furnishing primary care services be no less than 100% of Medicare payment rates in 2013 and 2014. Reconciliation Act section 1202 also provides 100% federal funding for the incremental costs to states of meeting this requirement.

Subtitle D covers other improvements to Medicaid services, including:

- Requiring coverage of services provided by free-standing birth centers. (Sec. 2301)
- Allowing children who are enrolled in either Medicaid or CHIP to receive hospice services without foregoing curative treatment related to a terminal illness. (Sec. 2302)
- Clarifying that "medical assistance" encompasses both payment for services provided and the services themselves. (Sec. 2304)
- Adding a new policy under section 10202 that creates financial incentives for states to shift Medicaid beneficiaries out of nursing homes and into home- and community-based services (HCBS). The provision provides FMAP increases to states to rebalance their spending between nursing homes and HCBS. (Sec. 10202)

The PPACA contains a number of additional sections covering support for parenting and pregnant teens and women, including:

- Defining "eligible institution of higher learning" as having the same meaning as in section 101 of the Higher Education Act of 1965 (20 U.S.C. § 1001). The terms "accompaniment," "community service center," "high school," "intervention service," "Secretary," "state," "supportive social service," and "violence" are also defined. (Sec. 20211)

- Establishing a Pregnancy Assistance Fund for the purpose of awarding competitive grants to states to assist pregnant and parenting teens and women. The fund will be established by the Secretary in coordination and collaboration with the Secretary of Education. (Sec. 10212)
- Requiring states to use the funds provided by these grants to provide support to pregnant and parenting teens and young women. States may use the funds provided to make funding available to eligible institutions of higher learning. (Sec. 10213)
- Requiring eligible institutions of higher learning that receive funding under this provision to contribute non-federal funds equal to 25% of the amount of funding provided to them. The amount contributed may be in cash or in-kind. (Sec. 10213)
- Defining that permissible uses of funds include for programs such as those that help pregnant or parenting teens stay in or complete high school, assistance to states in providing intervention services, and outreach so that pregnant and parenting teens and women are aware of services available to them. (Sec. 10213)
- Appropriating \$25 million for each of the FYs 2010 through 2019. (Sec. 10214)

Subtitle E—New Options for States to Provide Long-Term Services and Supports

Community First Choice Option (Sec. 2401)

The PPACA, as amended by the Reconciliation Act, gives states the option, beginning October 1, 2011, to provide medical assistance for home- and community-based attendant services and supports for certain low income individuals who would otherwise require care in an institution. Under this program, known as the Community First Option, states may provide funding through a "person-centered" plan of services and supports that is based upon an assessment of the functional needs of the individual, and is agreed to by the individual or the individual's representative. Covered services would be limited to services to accomplish activities of daily living, instrumental activities of daily living, health-related tasks, back-up systems or mechanisms to ensure continuity of services (e.g., beepers), and voluntary training on how to select, manage, and dismiss attendants. The states could also cover expenditures for the costs for an individual to transition from a nursing facility or other institution to a community-based home setting. States would be required to establish Development and Implementation Councils comprised primarily of individuals with disabilities, as well as elderly individuals and their representatives, and provide "consumer-controlled" community-based services on a statewide basis without regard to age, type or nature of disability, severity of disability, or the form of home- and community-based attendant services and supports the individual requires. They must also establish continual quality assurance systems, and collect and report data to the Secretary. If a state met all of the program requirements, it would be entitled to increased federal matching funds for eligible services at an additional rate of 6 percentage points. States must submit a state plan amendment to offer the Community First Option.

The Secretary will be required to evaluate and report to Congress in an interim report (by December 31, 2013) and a final report (by December 31, 2015) on the effectiveness of the program in allowing individuals to lead independent lives to the maximum extent possible, the impact on the physical and emotional health of participants, and a comparative analysis of the cost of services provided under the Community First Choice versus the cost of care in a nursing facility or institution for mental disease.

Other Medicaid Provisions Promoting HCBS (Sec 2402-2406, Sec. 10202)

Among other things, the PPACA:

- Adds a new policy creating financial incentives for states to shift Medicaid beneficiaries out of nursing homes and into HCBS. Subject to certain conditions, the law increases the FMAP matching funds: (1) by 5% for states with less than 25% of their total expenditures for long-term services and supports for FY 2009, for HCBS that are seeking to "rebalance" their expenditures for HCBS with a target spending percentage of 25% by October 1, 2015, and (2) by 2% for other states with the target of rebalancing their expenditures for HCBS to 50% of all long-term services and supports to be HCBS by October 1, 2015. (Sec. 10202)
- Removes barriers to providing HCBS by directing the Secretary to issue regulations to give states options to provide HCBS through a state plan amendment to individuals with higher levels of need, rather than through a waiver, and to extend full Medicaid benefits to individuals receiving HCBS under a state plan amendment. (Sec. 2402)
- Extends the "Money Follows the Person Rebalancing Demonstration Project" five years through September 30, 2016, changes the eligibility requirements for individuals to participate in the project by reducing the time period that the individual must have been residing in a facility from six months to 90 consecutive days, and excludes short-term rehabilitation stays. (Sec. 2403)
- Requires states to apply spousal impoverishment rules to beneficiaries receiving HCBS for a five-year period, beginning January 1, 2014. (Sec. 2404)
- Provides funding of \$10 million for FYs 2010 to 2014 to state Aging and Disability Resource Centers for agency initiatives. (Sec. 2405)
- Expresses the Sense of the Senate that Congress should address long-term services and support services in a comprehensive way that guarantees elderly and disabled individuals the care they need, in the community as well as in institutions. (Sec. 2406)

Subtitle F—Medicaid Prescription Drug Coverage

Medicaid Drug Rebates (Sec. 2501)

The PPACA amends the Medicaid rebate statute (42 U.S.C. § 1396r-8) in a number of significant ways, including increases to the minimum Medicaid rebate percentages, increased "additional rebates" for new formulations of brand name drugs, the establishment of a maximum rebate

amount, and the extension of Medicaid rebates to Medicaid managed care organization utilization. In addition, as discussed further below, section 2503 of PPACA amends the definition of "average manufacturer price," which underlies Medicaid rebate and Public Health Service section 340B program pricing calculations.

Increased minimum rebates. Whereas the rebate statute currently requires minimum rebates equal to 15.1% of the average manufacturer price (AMP) for single source and innovator multiple source drugs, and 11% of AMP for noninnovator multiple source drugs, PPACA increases the minimum rebate percentages to 23.1% and 13%, respectively. However, the statute also creates a special rebate percentage of 17.1% for certain clotting factors and for drugs approved exclusively for pediatric indications. These provisions are effective with respect to drugs dispensed on or after January 1, 2010, although it is unclear whether the Centers for Medicare & Medicaid Services (CMS) will require such payments to be made with the upcoming 1Q2010 rebate payments. Notably, the statute also provides that, unlike current Medicaid rebates, the incremental savings associated with the increase to the minimum rebate percentage for brand name drugs will be retained solely by the federal government and not shared with the states. Manufacturers should consider the impact of these provisions on existing arrangements, such as state supplemental Medicaid rebate agreements.

Additional rebates for new formulations of brand name drugs. The rebate statute currently requires manufacturers to pay an "additional" rebate to the extent that a product's AMP increases faster than the consumer price index (CPI) since the time of the product's launch. Because each nine-digit national drug code (NDC) product is considered to be a unique product for purposes of the rebate statute, a new formulation of a product can effectively establish a new launch period and reduce the amount of the "additional" rebate. The statute changes this by requiring that, for "line extensions" of an oral solid dosage form of single source or innovator multiple source drugs, the additional rebate percentage is equal to the greater of (i) the additional rebate percentage calculated under existing law for the old product or (ii) the additional rebate percentage calculated for any strength of the original drug product. The statute defines a "line extension" as "a new formulation" of a drug "such as an extended release formulation."

Two key issues are likely to arise under the amended statute. First, it is not clear what constitutes a new "formulation" of a drug. For example, new formulations might include different ingredient sets, different strengths, or different dosage forms of a single chemical entity, even though these differentiators might not be considered to be "formulation" changes for purposes of the Food, Drug, and Cosmetic Act. Thus, manufacturers will need to consider their product portfolios carefully and implement crosswalks among related products to calculate the additional rebate correctly. Second, these amendments take effect for drugs paid for on or after January 1, 2010. Thus, it is important to recognize that "new" formulations for purposes of the amendments may include pre-existing formulations. Third, manufacturers should consider the utility of maintaining older formulations, or of managing end-of-life pricing

for those formulations. It is unclear, however, whether the withdrawal of an original formulation from the market (and eventually its removal from the manufacturer's rebate agreement) would actually have the effect of terminating potential additional rebate liability under this provision.

Maximum rebate cap. For the first time, Congress has established a maximum rebate amount equal to 100% of the average manufacturer price. This may reduce or eliminate rebate liability for older products that had significant "additional rebate" exposure. This provision likewise takes effect January 1, 2010.

Rebates for Medicaid Managed Care Organization (MCO) Utilization. The Medicaid rebate statute currently exempts from Medicaid rebate-requirements utilization dispensed through Medicaid managed care organizations. PPACA now requires manufacturers to pay rebates on that utilization. Specifically, the MCOs will be required to report utilization to the states, and that utilization will be included in the quarterly rebate invoices. It is unclear whether state invoices will differentiate fee-for-service and MCO utilization. Further, the statute does not otherwise restrict MCOs' ability to negotiate rebates directly, so manufacturers should review existing MCO arrangements. The statute does not contain a specific effective date for these provisions, though it is appropriate to assume that they could apply to 1Q2010 utilization in the absence of additional guidance.

Elimination of Exclusion of Coverage of Certain Drugs (Sec. 2502)

Effective January 1, 2014, this provision reverses the statutory exclusion of certain drugs from Medicaid coverage, and instead mandates that such drugs shall not be excluded from coverage. The drugs in question are barbiturates, benzodiazepines and agents when used to promote smoking cessation, including such agents approved by the Food and Drug Administration (FDA) through the over-the-counter monograph process.

Note that the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) provided that, on January 1, 2013, the Medicare Part D exclusion of benzodiazepines, and of barbiturates when used in the treatment of epilepsy, cancer or a chronic mental health disorder, will end; since the Part D statutory provisions cross-reference to the Medicaid statute, it appears that as of January 1, 2014, there will be no statutory limitations on Part D coverage of these products.

Providing Adequate Pharmacy Reimbursement (Sec. 2503)

Some background is necessary to understanding the changes in this section of the PPACA.

For "multiple source drugs" (i.e., generic drugs and the branded drugs to which they are equivalent), the Social Security Act provides that CMS must establish a federal upper reimbursement limit (federal upper limit or FUL) price that state Medicaid programs may not exceed with respect to their Medicaid reimbursement to pharmacies.

Prior to the Deficit Reduction Act of 2005 (DRA), FULs were established when there were at least three equivalent products, and CMS set the FUL at 150% of the lowest "published price" (typically wholesale acquisition cost or WAC) of the available products. The DRA changed this, providing that FULs would be calculated when there were two or more equivalent products, and would equal 250% of the lowest AMP. However, CMS's implementation of its regulation to effectuate this requirement has been enjoined by the District Court of the District of Columbia since December 2007, based upon the court's determination that CMS's regulation did not comply with the statutory definitions of "average manufacturer price" or "multiple source drug," and would cause pharmacies irreparable harm as a result of insufficient reimbursement.⁵

Pursuant to MIPPA, Congress prohibited CMS from implementing the DRA requirement until October 1, 2009, and provided that FULs would continue to be calculated using the old methodology up until that date.

Pursuant to the PPACA, Congress has redefined "average manufacture price" and "multiple source drug," and has established a new formula for calculating FULs. AMP is now defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to "retail community pharmacies" and by retail community pharmacies purchasing directly from manufacturers. However, the term expressly excludes a variety of items: customary prompt payment discounts extended to wholesalers; bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies (including distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs, such as medication compliance programs and patient education programs); reimbursement for recalled, damaged, expired or otherwise unsalable returned goods; and payments received from, or rebates and discounts provided to, pharmacy benefit managers, managed care organizations, mail order pharmacies, long-term care providers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy. Overall, the changes to the definition used by manufacturers in reporting AMPs to CMS today appear likely to increase reported AMPs—most notably, because of the exclusion of mail order purchases, and possibly as a result of the exclusion of certain wholesaler service fees.⁶

"Retail community pharmacy" is defined to include independent, chain, supermarket, and mass merchandiser pharmacies, but it specifically excludes mail order, nursing home, long-term care, hospital, clinic, charitable, and government pharmacies, as well as pharmacy benefit managers.

⁵ *National Association of Chain Drug Stores et al. v. Leavitt* (U.S. Dist. D.C., C.A. No. 1:07cv02017)

⁶ It bears emphasizing that the statute's clarifications relating to various wholesaler fees refer only to the calculation of AMP. Nevertheless, the amendments may lend some additional support to the conclusion that these types of fees may be considered to be "bona fide service fees" that may be excluded from Medicare Part B "average sales price" calculations.

The definition of "multiple source drug" is revised to require that a drug be available for purchase in the United States, rather than in the given state.

The new formula for FUL requires that the Secretary calculate FULs as "no less than 175% of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices...available for purchase by retail community pharmacies on a nationwide basis" (emphasis added). The Secretary is required to use a smoothing process for AMPs.

In addition to reporting AMPs, manufacturers are required to report to CMS the number of units of the product used to calculate its AMP; this data will be necessary to calculate weighted average AMPs determined on the basis of utilization. Rather than publishing the AMP for each manufacturer's drug, CMS will now be required to publish only the weighted average AMP.

The provisions technically go into effect October 1, 2010; however, as a practical matter, it appears impossible for CMS to calculate new FULs prior to January 1, 2011 at the earliest, since manufacturers will have until November 30, 2010 to report AMPs using the new definition and unit volume. It is unclear whether pharmacy reimbursement will go up or down under the new law, as compared with FULs currently in effect.

Subtitle G—Medicaid Disproportionate Share Hospital (DSH) Payments

Medicaid DSH Payments (Sec. 2551, Reconciliation Act Sec. 1203)

The PPACA substantially reduces each state's Medicaid DSH allotment beginning the first FY after FY 2012 (the trigger year) for which the Secretary determines (based upon the American Community Survey of the Bureau of the Census), that the percentage of uncovered/ uninsured individuals residing in the state is at least 45% less than the percentage of such individuals determined for the state for FY 2009. The 16 states considered "low DSH states" (generally, states with DSH expenditures between 0% and 3% of total Medicaid spending in FY 2000) will be reduced by 25%, and all other states will be reduced by 50%. Those portions of a state's Medicare DSH allotment that are diverted for the cost of coverage expansions under a waiver (in effect in July 2009) will not be subject to the reduction. A state's Medicaid DSH allotment will be reduced even further in subsequent years, with further drops in the percentage of uninsured individuals in the state. These subsequent reductions will be equal to the percentage reduction in uncovered individuals in the preceding FY multiplied by 25% (in "low DSH states"), or by 50% (in any other state). A state's allotment for FY 2013 and succeeding FYs will not be less than the amount equal to 35% of the DSH allotment determined for the state for FY 2012 increased by inflation.

Section 1203 of the Reconciliation Act amends section 2551 by changing the reduction in federal Medicaid DSH payments from \$18.1 billion to \$14.1 billion, and by moving the date the reductions commence back to FY 2014. The Reconciliation Act extends through FY 2013 the

federal DSH allotment for a state that has a \$0 allotment after FY 2011. Additionally, the Reconciliation Act directs the Secretary to develop a methodology for reducing federal DSH allotments to all states in order to achieve the mandated reductions.

Subtitle H—Improved Coordination for Dual Eligible Beneficiaries

Five-Year Period for Demonstration Projects (Sec. 2601)

The PPACA extends time frames for Medicaid waiver programs for dual eligibles under Sections 1115 or 1915 of the Social Security Act. These programs may be conducted for five years and extended for additional five-year periods (instead of the two-year periods under prior law) unless the Secretary determines that the conditions for the waiver have not been met or that it would no longer be cost-effective and efficient, or consistent with the purposes of the statute, to extend the waiver.

Providing Federal Coverage and Payment Coordination for Dual Eligible Beneficiaries (Sec. 2602)

Section 1602 requires the Secretary to establish, not later than March 1, 2010,⁷ a Federal Coordinated Health Care Office (Office), headed by a Director reporting to the Administrator of CMS. The purpose of the Office is to more effectively integrate benefits under Medicare and Medicaid, and improve the coordination between the federal government and states to ensure that Medicare/Medicaid dual eligibles obtain full access to the items and services to which they are entitled under the programs.

Goals of the Office include eliminating regulatory conflicts between rules under the Medicare and Medicaid programs, improving care continuity and safe and effective care transitions, and eliminating cost-shifting between the Medicare and Medicaid programs and related health care providers. Among other things, the Office is responsible for studying the provision of drug coverage for new dual eligible individuals, as well as for monitoring and reporting annual total expenditures, health outcomes, and access to benefits for all dual eligible individuals.

The Secretary is required to submit to Congress, as part of the administration's annual budget request, recommendations for legislation that would improve care coordination and benefits for dual eligible individuals.

⁷ Even though this date was in the past when the PPACA was enacted, it does not appear to have been changed in the Reconciliation Act.

Subtitle I—Improving the Quality of Medicaid for Patients and Providers

Adult Health Quality Measures (Sec. 2701)

Under the Children's Health Insurance Program Reauthorization Act of 2009 (Public Law 111-3) (CHIPRA), the Secretary was required to develop and publish an initial core set of health care quality measures for children enrolled in Medicaid or CHIP in order to assess the availability and effectiveness for care for children enrolled in these programs. Under the PPACA, the Secretary is instructed to publish a recommended core set of adult health quality measures for Medicaid-eligible adults, similar to the core set of child health quality measures required by CHIPRA. The PPACA has appropriated \$60 million in order to carry out this section for each of FYs 2010-2014.

The PPACA establishes a number of deadlines for publishing these core measures. The Secretary must publish by January 1, 2011, a recommended core set of adult health quality measures for comment, and by January 1, 2012, the Secretary must publish the initial core set of measures. No later than January 1, 2013, the Secretary and the states must develop a standardized format for states to report information based on the core measures and create procedures to encourage states to use such measures to voluntarily report information regarding the quality of health care for Medicaid eligible adults.

Under CHIPRA, the Secretary is required to make a report to Congress every three years on the status of the core set of child health quality measures, including information on various aspects of the Secretary's efforts to improve health insurance coverage for children, and recommendations for further legislative action. The PPACA requires that the Secretary include in this report information as it pertains to the core set of adult health quality measures. This report is to be made no later than January 1, 2014, and every three years thereafter.

Within 12 months after the Secretary releases the recommended set of core measures, the Secretary must establish a Medicaid Quality Measurement Program in the same manner as the Secretary establishes the corresponding pediatric quality measures program. The aggregate amount of funding awarded to the development of the program must equal the aggregate amount under the corresponding provisions of the CHIPRA program. Within two years after this program is established, and yearly thereafter, the Secretary must publish recommended changes to the initial core set of adult health quality measures to reflect the testing and consensus process for the development of the adult health quality measures.

The PPACA also requires certain states to make annual reports to the Secretary regarding state-specific information on the adult health quality measures and on the quality of health care furnished to Medicaid-eligible adults.

Payment Adjustment for Health Care-Acquired Conditions (Sec. 2702)

The PPACA defines a health care-acquired condition as a medical condition for which an individual was diagnosed that could be identified by a secondary diagnostic code described in 42 U.S.C. § 1395ww(d)(4)(D)(iv) (generally, conditions that could have been prevented through the application of evidence-based guidelines).

Under this section, the PPACA instructs the Secretary to identify current state practices that prohibit payment for these health care-acquired conditions and to incorporate the appropriate identified practices into the Medicaid regulations. These regulations, which are intended to be effective as of July 1, 2011, must prohibit payments to states under section 1903 of the Social Security Act.

Additionally, the PPACA instructs the Secretary to adapt and apply to state plans (or waivers) under Title XIX of the Social Security Act, the specific Medicare regulations that prohibit payment because of the presence of a secondary diagnosis code that are appropriate for application to the Medicaid program.

State Option to Provide Health Homes for Enrollees with Chronic Conditions (Sec. 2703)

Beginning January 1, 2011, the PPACA permits states to provide medical assistance to Medicaid recipients with chronic conditions who seek treatment in a "health home." A health home is defined as a designated provider, a team of health care professionals, or a health team (collectively "health home service providers") who provide health home services for eligible Medicaid recipients. These are defined as individuals with two chronic conditions, or one condition with a risk of having a second (e.g., substance use disorder, asthma, diabetes, heart disease, obesity) or a serious and persistent mental health condition. These services can include comprehensive care management, care coordination and health promotion, comprehensive transitional care, patient and family support, referral to community and social support services, and use of health information technology to link services. State payments to a health home service provider under this section will be considered medical assistance, except for the first eight FY quarters, during which the federal medical assistance percentage for the payments will be 90%.

Planning grants for states to develop a state plan amendment will be awarded starting January 1, 2011, and the maximum amount awarded to states will be \$25 million. States are required to outline their methodology for determining payment for home health services in the state plan amendment.

The PPACA also requires the state plan amendment to include a requirement for hospitals to outline procedures for referrals of eligible individuals with chronic conditions and requires a state's coordination with other agencies, like the Substance Abuse and Mental Health Services Administration.

States will be required to establish a methodology for tracking avoidable hospital readmissions, calculating savings resulting from improved management of chronic care, and proposing methods for using health information technology in providing health home services and improving care coordination. Finally, health home service providers will be required to report to the state on measures for determining the quality of services as a condition for receiving payment.

In order to assess the effect of these programs on reducing hospital admissions, emergency room visits, and admissions to skilled nursing facilities, the PPACA requires the Secretary to contract with an independent entity to gather and report on this information. Furthermore, the PPACA requires states that implement this health home program to report to the Secretary on the implementation of the program. The Secretary is also obligated to make various reports to Congress regarding the effects of the health home programs.

Demonstration Project to Evaluate Integrated Care Around a Hospitalization (Sec. 2704)

The PPACA requires the Secretary to implement a demonstration project, beginning January 1, 2012 and ending December 31, 2016, in up to eight states to evaluate the use of bundled payments for the provision of integrated care and concurrent physician services for a Medicaid recipient during hospitalization.

States selected to participate must specify what episodes of care they intend to address. Medicaid recipients are not liable for additional costs as a result of this project, and payments made under the demonstration project will be adjusted for the characteristics of the individuals targeted by the project. Additionally, hospitals involved in the demonstration project must use robust discharge planning programs to provide for post-acute care for Medicaid recipients. The PPACA also prohibits the demonstration project from reducing the care for Medicaid.

States will be required to report to the Secretary the results of their evaluations, and within a year after the conclusion of the demonstration project, the Secretary will report to Congress on the results.

Medicaid Global Payment System Demonstration Project (Sec. 2705)

In the Medicaid Global Payment System Demonstration Project, the Secretary will work with the newly created Center for Medicare and Medicaid Innovation (CMI) (discussed later under Title III) to select a maximum of five states that will adjust payments made to an eligible safety net hospital system or network, in order to transition from a fee-for-service payment model to a global capitated payment model. This project will last from FYs 2010 through 2012.

During the project, the CMI must evaluate the results of the project to examine changes in health care quality outcomes and spending by the eligible safety net hospital systems or networks. Moreover, within 12 months after the project is completed, the Secretary will report to Congress the results and recommend legislative and administrative action.

Pediatric Accountable Care Organization Demonstration Project (Sec. 2706)

The Pediatric Accountable Care Organization Demonstration Project, which will last from January 1, 2012 to December 31, 2016, authorizes a participating state to allow pediatric medical providers that meet specified requirements to be recognized as an accountable care organization (ACO) in order to receive incentive payments. States may apply to participate in this program.

ACOs – new entities discussed under Title III, below – will agree to participate in the project for at least 3 years, and the Secretary, participating states, and pediatric providers must establish guidelines to ensure that the quality of care by the participating accountable care organizations is not compromised by participating in the program.

The PPACA requires that each participating state and the Secretary establish an annual minimal level of savings in expenditures for services covered by Medicaid and the CHIP program. Accountable care organizations that comply with the quality of care guidelines are entitled to a portion of the excess savings that they achieve.

Medicaid Emergency Psychiatric Demonstration Project (Sec. 2707)

The PPACA requires the Secretary to establish a demonstration project that will be conducted over three consecutive years so that participating states that have been selected by the Secretary can provide Medicaid payment to certain "institutions for mental diseases" for the provision of medical assistance to Medicaid beneficiaries between the ages of 21 and 61 who require medical assistance to stabilize an emergency medical condition. The PPACA defines an emergency medical condition as one in which an individual expresses homicidal thoughts or gestures, if determined dangerous to self or others.

The state is responsible to ensure that institutions participating in the demonstration will determine, before the individual's third day of inpatient stay, whether or not the individual has been stabilized. Payments for this demonstration project are limited to \$75 million, and must be made by December 31, 2015. As a condition of receiving payment, states must report information about the demonstration as required by the Secretary. Finally, the Secretary must report to Congress on the outcome of the demonstration, including various assessments related to the project.

Subtitle J—Improvements to the Medicaid and CHIP Payment and Access Commission (MACPAC)

MACPAC Assessment of Policies Affecting All Medicaid Recipients (Sec. 2801)

This subtitle elaborates on the matters to be examined by the Medicaid and CHIP Payment and Access Commission (MACPAC), a new federal agency established under the CHIP Reauthorization Act of 2009 to review Medicaid and CHIP access and payment policies, and to

advise Congress on a wide range of topics affecting Medicaid and CHIP. Issues for MACPAC consideration set out under the PPACA include eligibility and coverage policies, enrollment and retention processes, quality of care, analysis and reporting on state-specific data, the interaction between Medicare and Medicaid, MACPAC membership criteria, the impact of grants to implement alternatives to current tort litigation, and consultation and coordination with other state and federal agencies, including the Medicare Payment Advisory Commission upon which the MACPAC was modeled. The PPACA would also authorize \$11 million in funding for MACPAC in FY 2010.

Subtitle K—Protections for American Indians and Alaska Natives

Among other things, the PPACA:

- Establishes special rules for Native Americans enrolled in qualified health care coverage in the individual market through state exchanges. (Sec. 2901)
- Amends, revises, and extends the Indian Health Care Improvement Act. (Sec. 10221)
- Eliminates the reimbursement sunset for Medicare Part B services furnished by certain Indian hospitals and clinics. (Sec. 2902)

Subtitle L—Maternal and Child Health Services

Among other things, the PPACA:

- Attempts to reduce infant and maternal mortality by establishing a grant program for states, tribes, and territories that uses designated maternal, infant, and early childhood home visitation service delivery models targeted at at-risk populations and communities. (Sec. 2951)
- Seeks to address postpartum depression and psychosis through research, education, and support services provided by HHS, and through a grant program for public and nonprofit private entities. (Sec. 2952)
- Authorizes \$75 million per year from FY 2010 to FY 2014 for a "personal responsibility education grant program" for states, Indian tribes, and tribal organizations to educate youth on abstinence and contraception, and to develop other strategies to prevent teen pregnancy and sexually transmitted diseases. (Sec. 2953)
- Provides \$50 million per year through FY 2014 for abstinence education. (Sec. 2954)
- Requires states to provide children aging out of the foster care system with information on health insurance and a chance to designate someone other than a relative to hold a health care power of attorney or similar document for use if necessary on their behalf. (Sec. 2955)

Title III—Improving the Quality and Efficiency of Health Care

Subtitle A—Transforming the Health Care Delivery System

Part I—Linking Payment to Quality Outcomes under the Medicare Program

Hospital Value-Based Purchasing Program (Sec. 3001)

The Hospital Value-Based Purchasing (VBP) Program builds on Medicare's existing Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program that, since FY 2005, has provided differential payments to hospitals that meet certain requirements, including publicly reporting their performance on a defined set of inpatient care performance measures. In addition to giving hospitals a financial incentive to report on the quality of their services, the RHQDAPU program has provided CMS with quality of care information, some of which CMS has made publicly available on the Hospital Compare website at www.hospitalcompare.HHS.gov.⁸

In November 2007, CMS presented Congress with a "Plan to Implement a Medicare Hospital Value-Based Purchasing Program." At that time, CMS proposed to replace the RHQDAPU program with a new program that would include both public reporting and financial incentives for better performance, in an effort to "transform Medicare from a passive payer of claims to an active purchaser of care."⁹ Under the plan proposed, payments to high-performing hospitals would be greater than payments to lower-performing hospitals.

Under the PPACA, the Hospital VBP program will make value-based incentive payments in a FY to hospitals that meet performance standards with respect to "measures" (other than measures of readmissions) selected by the Secretary. The Hospital VBP program will begin in FY 2013 and apply to payments for discharges occurring on or after October 1, 2012. For FY 2013, the measures are to cover at least the following five conditions or procedures: (1) acute myocardial infarction (AMI), (2) heart failure, (3) pneumonia, (iv) surgeries, as measured by the Surgical Care Improvement Project; and (v) health care-associated infections, as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan).

⁸ The RHQDAPU program was originally mandated by section 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which authorized CMS to pay hospitals that successfully reported designated quality measures a higher annual update to their payment rates. Initially, the MMA provided for a 0.4 percentage point reduction in the annual market basket update for hospitals that did not successfully report. The Deficit Reduction Act of 2005 increased that reduction to 2.0 percentage points. CMS reports that in FY 2009, 96% of hospitals participated successfully in the reporting program and received the full market basket update for FY 2010.

⁹HHS, Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program, November 21, 2007.

For FY 2014 and thereafter, the measures selected must include efficiency measures, such as measures of Medicare spending per beneficiary. The measures may be adjusted for factors such as age, sex, race, severity of illness and other factors that the Secretary determines appropriate. Effective for payments beginning with FY 2013, the Secretary is also to provide for appropriate risk adjustment with regard to quality measures for outcome of care to maintain incentives for hospitals to treat patients with severe illness or conditions.

Although the Secretary is to have considerable discretion in determining the measures appropriate for the measurement of quality of care, the Social Security Act (42 U.S.C. § 1395ww(b)(3)(B)(viii)) already provides for the Secretary to adopt a baseline set of performance measures set forth in the November 2005 report by the Institute of Medicine of the National Academy of Sciences under section 238(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, as well as other measures that reflect those adopted by national consensus building entities. Under the PPACA, the measures are also to relate to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, developed by CMS, which collects patients' perspectives on hospital care.¹⁰

The PPACA requires the Secretary to establish standards to evaluate performance for the measures selected for a performance period for a FY. The performance standards, which are to include levels of achievement and improvement, will be announced at least 60 days before the beginning of the performance period for the FY involved. In establishing the performance standards, the Secretary is to take into account practical experience with the measures involved, historical performance standards, improvement rates and opportunity for continued performance.

Hospitals will be given a performance score, assessing their total performance. A hospital's performance score will be determined using the higher of its achievement or improvement score, presumably reflecting Congress' objective not only to reward good performance but also to encourage improvement.¹¹ If a hospital meets or exceeds the performance standards for the performance period for a FY, the Secretary will increase the base operating diagnosis related group (DRG) payment for the hospital for each discharge occurring in such FY by the value-based incentive payment amount. Hospitals that achieve the highest hospital performance scores will receive the largest value-based incentive payments.

¹⁰ The HCAHPS survey solicits patient perspectives on care, asking patients to rate their experiences with regard to such topics as communication with doctors, communication with nurses, responsiveness of hospital staff, pain management, communication about medicines, discharge information, cleanliness of the hospital environment and quietness of the hospital environment.

¹¹ In its 2007 Report to Congress, CMS observed that rewarding only the best performance would leave hospitals needing the greatest improvement with little opportunity to earn incentives, potentially causing them to stagnate or fall further behind in relative performance. Alternatively, rewarding only improvement would provide little or no recognition for hospitals that have already attained high levels of performance. CMS Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program, November 21, 2007, p. 4.

The value-based incentive payments will be funded by reducing the base operating DRG payment amount for all hospitals in the FY involved for each discharge by the applicable percentage, beginning with FY 2013. The applicable percentage will be 1% in FY 2013, 1.25% in FY 2014, 1.5% in FY 2015, 1.75% in FY 2016, and 2% in FY 2017 and succeeding years. Portions of Medicare payments attributable to outliers, indirect medical education, disproportionate share and low volume will not be affected. There are also special rules for sole community hospitals and Medicare-dependent small rural hospitals. The total amount available for value-based incentive payments for all hospitals for a FY will be equal to the total amount of reduced payments for all hospitals for such FY.

Hospitals will be informed of the adjustments to be made at least 60 days prior to the FY involved for discharges occurring in such FY. Importantly, the value-based incentive payment and the payment reduction shall each apply only with regard to the specific FY involved. The Secretary may not take into account such value-based incentive payment or payment reduction in making payments to a hospital in a subsequent FY.

Certain hospitals will be excluded from the VBP program in a FY. These include hospitals subject to payment reduction for failure to report quality data as required, hospitals that have been cited for deficiencies that pose immediate jeopardy to the health or safety of patients, and hospitals for which there are not a minimum number of measures or cases that apply to the hospital for the performance period for the FY.

The Secretary will use the Hospital Compare website to make available to the public information relating to the performance of each hospital under the VBP program, including the performance of the hospital with respect to each measure that applies to the hospital, the performance of the hospital regarding each condition or procedure, and the hospital performance score assessing the total performance of the hospital. Hospitals will have an opportunity to review and submit corrections for the information to be made public. The Secretary will also post aggregate information about the VBP program, including the number of hospitals receiving value-based incentive payments, the range and total amount of such payments, and the number of hospitals receiving less than the maximum value-based incentive payment.

Hospitals will have a mechanism to appeal the calculation of their performance assessment and their performance score. The appeal process appears to be very limited, however, because administrative and judicial review will not be available to challenge most aspects of the program, including: the methodology used to determine the amount of the value-based incentive payment; the determination of the amount of funding available for the value-based incentive payments; reduction of the base operating DRG amount; the establishment of the performance standards and the performance period; the measures specified; and the methodology developed to calculate hospital performance scores. The Secretary will promulgate regulations to carry out the VBP program.

The GAO is to evaluate and make an interim report on the performance of the hospital VBP program not later than October 1, 2015. The study is to analyze the impact of the program on the quality of care furnished to Medicare beneficiaries, expenditures under the Medicare program, quality performance among safety net hospitals, and any barriers such hospitals face in meeting the performance standards. Similarly, the Secretary is to conduct a study of the program, including ways to improve the hospital VBP program and ways to address any unintended consequences that may occur as a result of the program. The Secretary is also to evaluate whether the program resulted in lower spending under the Medicare program, or financial savings. The Secretary's report is to be submitted to Congress no later than January 1, 2016, together with recommendations for legislation and administrative action.

Physician Quality Reporting Initiative Provisions (Sec. 3002, 10327, 10331)

Under the Physician Quality Reporting Initiative (PQRI), which was originally authorized by the Tax Relief and Health Care Act of 2006, eligible professionals who satisfactorily report data on specified quality measures for covered professional services can receive an incentive payment equal to a percentage of their total allowed charges for covered services during the reporting period (subject to a cap). Authority for PQRI bonus payments was extended by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) through 2010.

The PPACA extends PQRI bonus payments through 2014, with the bonus level set at 1% in 2011 and 0.5% in 2012-2014. Beginning in 2014, eligible professionals who do not satisfactorily submit quality information will face a penalty, resulting in reduced rates beginning in 2015. The payment penalty is equal to 1.5% in 2015, increasing to 2% in 2016 and subsequent years.

The PPACA also establishes a separate 0.5% PQRI bonus payment in 2011 through 2014 for eligible professionals who successfully report quality measures through a new Maintenance of Certification Program (MOCP) and meet certain other specified criteria. A MOCP program is defined as a continuous assessment program "that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning, interpersonal and communication skills and professionalism."

In addition, the PPACA requires the Secretary to provide timely feedback to eligible professionals on their performance with regard to satisfactorily submitting data on quality measures. Moreover, the law requires the Secretary to establish by January 1, 2011, an "informal" process for eligible professionals to seek a review of the determination that the professional did not satisfactorily submit quality measures under the PQRI. The PPACA also requires the Secretary to develop a plan by January 1, 2012, to integrate the PQRI program with the standards for meaningful use of certified electronic health records under the ARRA.

In a related provision, section 10331 requires the Secretary to develop a "Physician Compare" website by January 1, 2011, with information on physicians and other eligible professionals who participate in the PQRI. The Secretary also is required, not later than January 1, 2013, to implement a plan for making publicly available through Physician Compare, certain information on Medicare physician performance that provides comparable information on quality and patient experience measures. A series of conditions are established for release of such data, including, among others, a determination that such data is statistically valid and provides a robust and accurate portrayal of a physician's performance, and an opportunity for physicians to review the information before it is made public. The Secretary also must take into account the plan to transition to a value-based purchasing program for physicians and other practitioners developed under MIPPA.

Improvements to the Physician Feedback Program (Sec. 3003)

MIPPA required the Secretary to establish a "Physician Feedback Program," under which the Secretary will use Medicare claims data to provide physicians with confidential reports regarding their resource use in treating Medicare patients.¹² The PPACA modifies and expands this program by, among other things, specifying that the Secretary use claims data in developing reports on resource use, and permitting the Secretary to include information on quality of care in the reports. The law also provides for reporting on resource utilization through the development of an "episode grouper," which combines separate but clinically related items and services into an episode of care for an individual, as appropriate. The Secretary must develop the episode grouper by January 1, 2012, and make it available to the public and subject to review and endorsement by an appropriate consensus-based entity. Beginning with 2012, the Secretary will use associated data to provide reports to physicians comparing patterns of resource use of the individual physician with that of other physicians. The data in the report must be adjusted for a number of factors, including socioeconomic and demographic characteristics, ethnicity, and health status of individuals, and geographic payment differences.

Quality Reporting for LTCHs, IRFs, Psychiatric Hospitals, Hospices, & Cancer Hospitals (Sec. 3004-3005, 10322)

The PPACA establishes new Medicare "pay for reporting" provisions for a number of provider types that currently are not required to report quality data to CMS: long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), psychiatric hospitals, and hospices. For each type of provider, the Secretary will specify the quality measures, which generally must be endorsed by a quality measure consensus-based entity. Entities that do not submit data on the

¹² For an update on CMS implementation of this program, which CMS calls the "Physician Resource Use Measurement & Reporting Program," see the final Medicare physician fee schedule rule for CY 2010, available at <http://edocket.access.gpo.gov/2009/pdf/E9-26502.pdf> (beginning at page 61844).

specified quality measures in the form and manner mandated by the Secretary will experience a reduction in their annual update equal to 2 percentage points. The reduction can result in less than a 0% payment update and payment rates that are less than the prior year. However, any reductions would not carry over into subsequent years. With regard to LTCHs and psychiatric hospitals, the Secretary must publish quality measures by October 1, 2012, and each LTCH and psychiatric hospital must submit their respective quality data beginning with rate year 2014. For IRFs and hospices, the measures will be published by October 1, 2012, and IRFs and hospices must report their respective measures by FY 2014. The Secretary also is required to establish a process for making the quality data available to the public, although reporting providers would have an opportunity to review the data prior to public release.

Likewise, the PPACA requires the Secretary to establish quality reporting programs for cancer hospitals exempt from the inpatient prospective payment system (IPPS). The Secretary must publish relevant measures by October 1, 2012, which must be reported by hospitals in the form and manner specified by the Secretary beginning with FY 2014. Note that this provision does not include a market basket reduction penalty for hospitals that fail to report data. The Secretary must establish a process for making the quality data available to the public, after hospitals have had an opportunity to review their information.

Plans for a Value-Based Purchasing Program for Skilled Nursing Facilities, Home Health Agencies, and Ambulatory Surgical Centers (Sec. 3006, 10301)

This section of PPACA directs the Secretary to submit a plan to Congress by FY 2012 outlining how to effectively move skilled nursing facilities (SNFs) and home health agencies (HHAs) into a value-based purchasing payment system. As with the PPACA provisions applicable to hospitals, CMS has been operating a value-based purchasing demonstration project since 2009 for SNFs.¹³ Under value-based purchasing, as with the PPACA provisions applicable to hospitals, CMS assesses the performance of a provider based on selected quality measures. CMS will then make incentive payment awards to those providers that perform the best or improve the most in terms of quality.

As amended by section 10301, PPACA similarly requires the Secretary to develop a plan to reimburse ambulatory surgery centers (ASCs) based on the quality and efficiency of care delivered in ASCs.

¹³ From the CMS Overview of the Demonstration Project:

"Each year of the demonstration, CMS will assess each participating nursing home's quality performance based on 4 domains: staffing, appropriate hospitalizations, minimum data set (MDS) outcomes, and survey deficiencies. CMS will award points to each nursing home based on how they perform on the measures within each of the domains. These points will be summed to produce an overall quality score. For each State, nursing homes with scores in the top 20% and homes that are in the top 20% in terms of improvement in their scores will be eligible for a share of that State's savings pool." The demonstration began July 1, 2009 in three states.

The plan must consider the following: (1) the development, selection, and modification process of measures to the extent feasible and practical of all dimensions of quality and efficiency; (2) the reporting, collection, and validation of quality data; (3) the structure of proposed value-based payment adjustments, including the determination of thresholds or improvements in quality that would substantiate a payment adjustment, the size of such payments, and the sources of funding for the value-based bonus payments; (4) methods for publicly disclosing performance information on performance; and (5) any other issues as determined by the Secretary. In developing each plan, the Secretary would be required to consult with relevant stakeholders and take into consideration experiences with demonstrations that are relevant to value-based purchasing in SNFs.

This section and the bundling section are two significant prongs in what could eventually become a new Medicare payment system. Historically, Congress created the prospective payment system for acute-care hospitals in the early 1980s, but no additional prospective payment systems were created under Part A until the Balanced Budget Act of 1997 and the creation of the SNF prospective payment system (PPS). Since that time, CMS has moved all formerly cost-based Part A providers to a PPS.

One feature of the SNF PPS is the assessment and collection of patient data via the MDS, which is a much more sophisticated mechanism of measuring patient acuity than is found in the acute-care hospital PPS – a system based on ICD-9-CM diagnosis and procedure codes. This data, with some modification, is suitable for use in an alternative payment system where quality outcomes are tied to payment – a stated policy goal of CMS for several administrations. In fact, this is one of many demonstration and other quality-related initiatives that have been implemented over the past five years. In other words, it is no secret that CMS would like to be able to pay and evaluate all providers on the basis of quality. Under the current system, providers are required to meet certain minimum standards for participation, but are not evaluated or ranked on the basis of outcomes.¹⁴ This provision is the first step in what will likely be a lengthy debate over a new model for Medicare payment systems.

Value-Based Payment 'Modifier' under the Physician Fee Schedule (Sec. 3007, 10327)

The PPACA requires the Secretary to develop and implement a budget-neutral payment adjustment – referred to as a "payment modifier" – that will vary Medicare payments to physicians and physician groups based on the quality and cost of the care they deliver. The payment modifier will be risk-adjusted and geographically standardized. Quality and cost of care will be evaluated, to the extent practicable, based on composites of appropriate measures established by the Secretary and endorsed by a consensus organization contracting with the

¹⁴ CMS has implemented, however, a ranking system for SNFs called the 5-Star system that is based upon compliance with those minimum standards. See *Zagats for Healthcare: Will the Government Start Rating All Providers?* at http://www.healthlawyers.org/News/Connections/CurrentIssue/Documents/2009%20Features/HLN0906_Feature.pdf

Secretary. Quality measures could include those that reflect health outcomes,¹⁵ while cost measures (based on expenditures per individual) may reflect risk factors such as socioeconomic and demographic characteristics, ethnicity, and individual health status.

The Secretary must publish the specific cost and quality measures by January 1, 2012, and begin implementing the payment modifier through the 2013 physician fee schedule rulemaking process. The Secretary must specify an initial performance period for application of the payment modifier, during which the Secretary will, to the extent practicable, provide information to physicians on their quality of care compared with cost. Payment adjustments will be phased in over two years; the Secretary must apply the payment modifier for items and services furnished beginning on January 1, 2015, for specific physicians and physician groups as the Secretary determines appropriate, and apply it not later than January 1, 2017, for all physicians and physician groups.¹⁶ In applying the modifier, the Secretary is directed to promote systems-based care as appropriate, and take into account the special circumstances of physicians in rural areas and other underserved communities. The Secretary also must coordinate the physician payment modifier with the Physician Feedback Program and other similar value-based purchasing reforms.

Payment Adjustment for Conditions Acquired in Hospitals (Sec. 3008)

The PPACA continues a focus on hospital-acquired conditions, which began with section 5001(c) of Deficit Reduction Act of 2005. That section requires the Secretary to identify conditions that: (a) are high cost or high volume or both, (2) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (3) could reasonably have been prevented through the application of evidence-based guidelines.

CMS has selected 10 categories of conditions for the hospital-acquired conditions payment provision to date. These include:

1. Foreign Object Retained After Surgery
2. Air Embolism
3. Blood Incompatibility
4. Stage III and IV Pressure Ulcers
5. Falls and Trauma
 - Fractures
 - Dislocations
 - Intracranial Injuries
 - Crushing Injuries
 - Burns
 - Electric Shock

¹⁵ Under section 10327, the Secretary may incorporate participation and successful completion in an MCOP into the quality composite measure for years after 2014.

¹⁶ Beginning in 2017, the Secretary also may apply this policy to other eligible professionals besides physicians.

6. Manifestations of Poor Glycemic Control
 - Diabetic Ketoacidosis
 - Nonketotic Hyperosmolar Coma
 - Hypoglycemic Coma
 - Secondary Diabetes with Ketoacidosis
 - Secondary Diabetes with Hyperosmolarity
7. Catheter-Associated Urinary Tract Infection (UTI)
8. Vascular Catheter-Associated Infection
9. Surgical Site Infection Following:
 - Coronary Artery Bypass Graft (CABG) – Mediastinitis
 - Bariatric Surgery
 - Laparoscopic Gastric Bypass
 - Gastroenterostomy
 - Laparoscopic Gastric Restrictive Surgery
 - Orthopedic Procedures
 - Spine
 - Neck
 - Shoulder
 - Elbow
10. Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)
 - Total Knee Replacement
 - Hip Replacement

The PPACA provides that, effective FY 2015, acute care hospitals shown to be in the top quartile of hospital-acquired conditions – relative to a risk-adjusted national average – will receive 99% of the DRG payment that would otherwise apply to their discharges for such FY. Prior to FY 2015, the Secretary will provide hospitals with confidential reports regarding their hospital-acquired conditions' experience during the applicable period.

The PPACA requires the Secretary to make information available to the public regarding a hospital's hospital-acquired conditions. Hospitals will be given the opportunity to review and submit corrections before such information is made public. The information will be posted on the Hospital Compare Internet website. Judicial and administrative review is precluded with regard to establishment of the top quartile, the specification of hospital-acquired conditions, and the specification of the applicable period.

The PPACA requires the Secretary to conduct a study on expanding the health-care-acquired conditions policy to payments made to other facilities under the Medicare program, including payments made to IRFs, LTCHs, hospital outpatient departments and other hospitals excluded from the inpatient prospective payment system, SNFs, ASCs, and health clinics. A report containing the results of the study, together with recommendations for legislation and administrative action, is to be submitted to Congress not later than January 1, 2012.

Value-Based Purchasing Pilot Program (Sec. 10326)

The PPACA requires the Secretary to conduct a Medicare pilot program establishing value-based purchasing programs for certain Medicare providers by January 1, 2016. The providers subject to this pilot program are: psychiatric hospitals and psychiatric units, LTCHs, IRFs, PPS-exempt cancer hospitals, and hospice programs. Current Medicare requirements may be waived as necessary for purposes of conducting the pilot, but Medicare spending may not increase as a result of the pilot program. After January 1, 2018, the Secretary may expand the duration and scope of a pilot program if such expansion would reduce Medicare spending while improving (or not reducing) quality of care, and the Secretary determines that such expansion would not limit Medicare benefits.

Availability of Medicare Data for Performance Measurement (Sec. 10332)

The PPACA authorizes the Secretary to release to qualified entities standardized extracts of Medicare claims data under Parts A, B, and D to evaluate the performance of providers and suppliers, effective January 1, 2012. In releasing such data, the Secretary must protect the identity of beneficiaries. Any performance reports generated using such data must meet a series of standards, including being made available confidentially to any provider or supplier identified prior to public release. Reports on data released to a qualified entity are not subject to discovery or admission as evidence in judicial or administrative proceedings without the consent of the applicable provider or supplier.

Part II—National Strategy to Improve Health Care Quality

Development of National Strategy (Sec. 3011-3012, 10302)

The PPACA requires the Secretary to use a transparent, collaborative process to establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health. The President is directed to convene an "Interagency Working Group on Health Care Quality" comprised of representatives of federal agencies to assist in the development and dissemination of this strategy.

As part of this process, the Secretary is directed to identify national priorities for improvement, focusing on priorities that: have the greatest potential for improvements in health outcomes, efficiency, and patient-centeredness of health care; have the potential for rapid improvements in care; address gaps in quality, efficiency, comparative effectiveness information,¹⁷ health outcomes measures, and data aggregation techniques; emphasize quality and efficiency in federal payment policy; enhance the use of health care data to improve quality, efficiency, transparency, and outcomes; address care for patients with high-cost chronic diseases; improve

¹⁷ Section 10302 clarifies that the limitations on the use of comparative effectiveness data in Medicare coverage policy established under section 6301 of the PPACA also apply to the development of the National Strategy for Quality Improvement.

patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections; and reduce health disparities, along with other areas the Secretary determines to be appropriate.

By January 1, 2011, the Secretary must develop a comprehensive strategic plan to achieve the priorities identified, addressing such issues as coordination among agencies, establishment of benchmarks, reporting requirements, and strategies to align public and private payers with regard to quality and patient safety. The national strategy must be submitted to Congress and updated at least annually. The Secretary also is required to establish a website no later than January 1, 2011 to make publicly available information on the national priorities and strategy.

Quality and Efficiency Measures (Sec. 3013-3014, 10303-10305)

The PPACA authorizes \$75 million for each of FYs 2010 through 2014 for the development of quality measures and outcomes measures, according to specific criteria.¹⁸ The PPACA directs the Secretary to award grants, contracts, or intergovernmental agreements for the purpose of developing or improving such quality measures, focusing on areas where no quality measures exist, and/or where existing quality measures need improvements, consistent with the national strategy. The measures must be updated at least every three years.

Likewise, the PPACA calls for the Secretary to develop and periodically update provider-level outcome measures for hospitals and physicians (and other providers as appropriate). Such measures can include: (1) outcome measurement for acute and chronic diseases, including the five most prevalent and resource-intensive acute and chronic medical conditions; and (2) outcome measurement for primary and preventive care, including measurements addressing distinct patient populations. The Secretary is directed to develop at least 10 measures for acute and chronic diseases within two years of enactment, and at least 10 measures for primary and preventive care within three years.

The PPACA also requires the Secretary, to the extent practicable, to publicly report on measures for hospital-acquired conditions that are currently used by CMS for purposes of adjusting Medicare hospital payments. In addition, the new law requires the Secretary to implement the best methods for developing clinical practice guidelines as identified in a MIPPA-mandated Institute of Medicine study.

In addition, section 3014 of the PPACA provides \$20 million for each of FYs 2010 through 2014 to support the development and use of endorsed quality and efficiency measures, including measures to satisfy quality reporting and payment policies applicable to specified types of Medicare providers. The PPACA establishes a process for the selection and periodic reassessment of such

¹⁸ For purposes of the PPACA, quality measure is defined as a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services.

measures, including a series of transparency provisions and requirements for consideration of the input of new multi-stakeholder groups. The Secretary must establish a process for disseminating the quality and efficiency measures.

Data Collection and Public Reporting (Sec. 3015, 10305)

The PPACA requires the Secretary develop and implement a plan to collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery, which will be used to implement the public reporting of performance information. Such performance information must be posted on public, standardized websites, and be tailored to respond to the needs of different stakeholders, including providers, patients, researchers, and policymakers. The performance information should include provider-specific information as appropriate.

Part III—Encouraging Development of New Patient Care Models

Establishment for Center for Medicare and Medicaid Innovation within CMS (Sec. 3021, 10306)

As background, the Social Security Amendment of 1967, as amended by the Social Security Amendments of 1972, gave the Secretary broad authority to develop and use experiments and demonstrations to test new approaches to delivering health care, paying providers, and providing benefits to beneficiaries of federal health care programs. Historically, all demonstrations must be budget-neutral and must be approved by the Office of Management and Budget (OMB) prior to implementation.

The PPACA expands the Secretary's authority to resolve health care financing issues and to develop innovative methods for the administration of Medicare and Medicaid. Section 3021 of the PPACA requires the Secretary to establish the Center for Medicare and Medicaid Innovation (CMI) within CMS by January 1, 2011. The purpose of CMI is to improve the quality and reduce the cost of care provided to beneficiaries of Medicare, Medicaid, and CHIP. The CMI will research, develop, test, and expand innovative and delivery arrangements to reduce program expenditures under federal health care programs while also preserving or enhancing the quality of care furnished to individual beneficiaries. In fulfilling its purpose, the CMI must consult with representatives from federal agencies, clinical and medical experts, health care management professionals, and states.

The Secretary must select models that address a defined population with poor clinical outcomes or avoidable expenditures. The models must also improve the coordination, quality, and efficiency of health care services furnished to such individuals. The PPACA gives the Secretary the authority to select models that address a variety of areas, including the following:

- Medical homes
- Alternative payment mechanisms
- Coordinated care

- Health information technology
- Medication management
- Patient education
- Integrated care for dually eligible beneficiaries
- Care for cancer patients
- Post-acute care
- Chronic care management
- Collaboration among mixed provider types
- Rural telehealth expansion
- Development of a rapid learning network

Notably, the Secretary cannot require initial budget neutrality as a condition for testing a CMI model.

Once a model enters the testing phase, the Secretary is required to evaluate: (1) the quality of care furnished under the model, including measurement of outcomes at the patient level, and (2) the impact on program spending. The Secretary may also establish requirements for states and other participating entities to collect and report information necessary to evaluate each model, and must make the results of each evaluation publicly available in a timely manner. Section 3021 requires the Secretary to terminate or modify the design and implementation of a model, if it does not meet one of the following three requirements: (1) improve quality without increasing spending; (2) reduce spending without reducing quality; or (3) improve quality and reduce spending. The Secretary has authority to expand the scope or duration of any model if: (1) the Secretary determines that expansion would reduce spending without reducing quality of care or improve quality of care and reduce spending, and (2) the Chief Actuary of CMS certifies that such expansion would reduce program spending.

Section 3021 also gives the Secretary authority to waive requirements under Titles XI and XVIII and sections 1902(a)(1), 1902(a)(13), and 1902(m)(2)(A)(iii) as necessary, to test the CMI models. The provision also exempts the testing, evaluation, and expansion of models from the Paperwork Reduction Act (PRA), which requires federal agencies to receive OMB approval for each collection of information request. There is also no requirement for congressional approval, which has delayed or disrupted previous Medicare demonstration projects.

The PPACA allocates the following amounts from unappropriated Treasury funds to the CMI:

- \$5 million for the design, implementation, and evaluation of models for 2010
- \$10 billion for 2011 through 2019
- \$10 billion for each subsequent 10-year fiscal period beginning with 2020

At least \$25 million of CMI's funds must go toward the design, implementation, and evaluation of specific models identified in the PPACA.

Beginning in 2012, the Secretary will be required to submit a report to Congress at least once every two years on the CMI's activities. The reports must include descriptions of the models tested, the number of Medicare and Medicaid participants, payment amounts made on behalf of participants, models chosen for expansion, and evaluation results. Reports must also include the Secretary's recommendations for legislative action to facilitate the development and expansion of successful models nationwide.

Medicare Shared Savings Program (Sec. 3022, 10307)

The PPACA requires the Secretary to establish a Medicare shared savings program by January 1, 2012. The purpose of this program is to encourage improved quality and cost-efficiency of health care delivered to Medicare fee-for-service beneficiaries (i.e., individuals enrolled in Medicare Parts A and B). Under Section 3022, each eligible accountable care organization (ACO) that takes responsibility for cost and quality of care will receive a portion of the savings it achieves for Medicare for those beneficiaries assigned to the ACO.

To be recognized as an ACO and to participate in the shared savings program, groups of providers and suppliers must meet certain statutory criteria, including quality measurements, patient-centeredness criteria, and threshold savings amounts for total per-beneficiary spending under Medicare Parts A and B. All ACOs eligible to participate in the shared savings program will also have an established mechanism from shared governance. Under section 3022, the types of groups and organizations eligible for the program are as follows:

- Physicians and practitioners (i.e., nurse practitioners, physician assistants, and clinical nurse specialists) in group practice arrangements
- Networks of individual practices of physicians or practitioners
- Partnerships or joint ventures between hospitals and physicians or practitioners
- Hospitals employing physicians or practitioners
- Other groups of providers or suppliers as the Secretary deems appropriate

ACOs may participate in the program only if they (1) include a sufficient number of primary care physicians and practitioners for the number of Medicare fee-for-service beneficiaries assigned to the ACO, and (2) have at least 5,000 such beneficiaries assigned to the ACO under section 3022.

Participating ACOs will enter a three-year agreement with the Secretary. The only difference between payment under the original Medicare fee-for-service program and payment under the shared savings program is that a participating ACO may receive additional payments for shared savings. During the three-year term of the agreement, an ACO will be eligible for a shared savings payment if the estimated average per-capita Medicare annual expenditures for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent below the benchmark the Secretary establishes for the ACO for each agreement period. An ACO that meets the expenditure requirements will receive a percentage (as determined by the Secretary) of the difference between the ACO's benchmark and the estimated average per-capita Medicare expenditures for that year. The program retains the remainder of the difference from savings.

To earn the shared savings payments, ACOs must also meet certain quality performance standards and submit pertinent data. The Secretary may terminate an agreement if an ACO does not meet the quality performance standards. Additionally, if the Secretary determines that an ACO has taken steps to avoid at-risk patients to reduce the likelihood of increasing costs, the Secretary may impose sanctions, including termination from the program.

Under section 10307 of the PPACA, the Secretary has flexibility to implement innovative payment models for participating ACOs. These include a partial capitation model, which may pose a financial risk for ACOs that are not highly integrated systems of care. Also, the Secretary cannot implement any payment model that would result in greater spending than would otherwise be expended if the model were not implemented.

National Pilot Program on Payment Bundling (Sec. 3023)

This provision directs the Secretary to develop a national, voluntary pilot program encouraging hospitals, doctors, and post-acute care providers to improve patient care and achieve savings for the Medicare program through bundled payment models. The program must be established by January 1, 2013 for a period of five years. In addition, the Secretary is required to submit a plan to Congress before January 1, 2016, to expand the pilot program if doing so will improve patient care and reduce spending. Section 10308 provides the Secretary authority to expand the payment bundling pilot if it is found to improve quality and reduce costs. Finally, the bill directs the Secretary to test bundled payment arrangements involving continuing care hospitals within the bundling pilot program.

Bundling is the second prong to possible Medicare payment reform. The current Medicare paradigm is separate payment – one payment for the facility and one payment for the physician. Because payment is unique to each site of service, providers do not have financial incentives to provide care that will reduce costs in other locations. Bundling is the idea that payment should be linked to the entire episode of care.

For example, assume a patient presents for admission to an acute care hospital. When Congress created the PPS for acute care hospitals, it created a system that paid the hospital a single payment based upon the patient's discharge. No matter the hospital costs, the payment would remain the same given the same diagnosis and relevant hospital procedures.¹⁹ Therefore, the financial incentive was to discharge the patient as quickly as possible. While hospitals take great care to discharge patients appropriately, there has always been criticism that such a system could result in early discharges. In addition, there has been a criticism that hospital care is often merely sufficient to move the patient to discharge, rather than some other higher metric of care (because the hospital's responsibility ends at discharge). Lastly, because physicians are paid separately, there is no alignment of financial incentives between the physician and the hospital.

¹⁹ There are, of course, exceptions for outliers and other items.

Post-acute providers (who are the next step in the continuum of care) also have separate Medicare payment systems. In the SNF, for example, the system is a per diem PPS that is based upon acuity. So the higher the acuity of the patient, the more the SNF is paid because higher acuity patients require a higher level of resource. These are very different financial incentives that have been built into the system by the government, and providers have worked hard to adapt to an ever-changing environment. The criticism of the SNF payment structure, however, is that facilities may keep patients for longer than necessary and utilize more resources than necessary in taking care of the patient.

Therefore, the theory behind these demonstration projects is to find a model that better aligns interests over the entire episode of care. A key concept for CMS is to make all providers and physicians "responsible" during the episode of care. One proposed model would create a single DRG (the acute care payment unit) that includes all post-acute care. For example, payment would be made to the hospital for all of the required care. The hospital would be required to provide all care, to include post-acute care (focused on a window of 30 days from admission). Another model would bundle payment for the physician and the hospital together, for a single payment to cover all care.

There are, of course, many issues with these proposals. What about kickback concerns? Who controls these referrals? For example, when a rehabilitation patient is ready to leave the hospital, who decides whether the patient should go to a rehabilitation hospital or to an SNF? Would that decision be influenced by the cost differential between care at those two sites?

Bundling is also an important issue to watch because it has the ability to create significant consolidation within the industry. If a hospital receives one payment for all care, why would it contract with an SNF to provide a service under-arrangement when it might be able to re-designate a wing of the hospital as intended for less intensive services? In other words, many of the traditional models we consider when we think of various sites of service could be radically changed. Bundling is going to be a critical topic in the years to come, and providers should pay close attention to the various models proposed in the pilot program.

Independence at Home Demonstration Program (Sec. 3024)

Beginning no later than January 1, 2012, the Secretary must conduct a Medicare demonstration program for chronically ill Medicare beneficiaries to test a payment incentive and service delivery model that uses physician- and nurse-practitioner-directed home-based primary care teams. The goal of the demonstration program is to determine whether the model, which provides comprehensive, coordinated, continuous, and accessible care to high-need populations at home, will achieve the following goals:

- Reduce preventable hospitalizations
- Prevent hospital readmission
- Reduce emergency room visits

- Improve health outcomes commensurate with the beneficiaries' stage of chronic illness
- Improve efficiency of care
- Reduce cost of Medicare services
- Achieve beneficiary and family caregiver satisfaction

The Secretary will enter into agreements for shared savings with eligible "independence at home medical practices," which are legal entities comprised of an individual physician or nurse practitioner or a group of physicians and nurse practitioners that offers care as part of team of professionals with experience providing home-based primary care to chronically ill beneficiaries. The independence-at-home medical practices that have expenditures below the annual target spending level established by the Secretary (based on the amount the Secretary estimates would have been spent for services covered under Medicare Parts A and B in the absence of the demonstration) will qualify to receive incentive payments.

The staff of independence-at-home medical practices will make home visits and be available 24 hours per day, seven days per week, to implement individually tailored care plans that are designed to reduce expenditures and improve health outcomes for chronically ill Medicare beneficiaries. Each independence-at-home medical practice must provide services to at least 200 applicable beneficiaries during each year of the demonstration. The practices will also be required to report on quality performance standards as specified by the Secretary. Subject to performance on those quality measures, a qualifying independence-at-home medical practice will be eligible to receive an incentive payment if the estimated spending target exceeds the practice's actual annual expenditures for applicable beneficiaries. The incentive payments will be equal to a portion of the amount by which actual expenditures are estimated to be less than 5% less than the estimated annual spending target. However, if a practice fails to meet quality standards during any year in the demonstration program, or if the Secretary determines that a practice will not receive an incentive payment for the second of two consecutive years, the Secretary must terminate the agreement with that independence-at-home medical practice.

The agreements under the demonstration program cannot exceed a three-year term. The Secretary is required to conduct an independent evaluation of the program and submit to Congress a final report on the demonstration's best practices. Section 3024 of the PPACA requires that funds be transferred to the CMS Program Management Account from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The provision appropriates \$5 million for FYs 2010 through 2015 to administer the demonstration program

Community-Based Collaborative Care Network Program (Sec. 10333)

The PPACA gives the Secretary the authority to award entities with grants to develop networks of providers to deliver coordinated care to low-income populations. Each community-based collaborative care network must include (1) a hospital that meets the criteria set forth in section

1923(b)(1) of the Social Security Act, and (2) all federally qualified health centers (FQHC) in the community. The grantees can use the funds for the following:

- Assist low-income individuals to access and appropriately use health services, enroll in health coverage programs, and obtain a regular primary care provider or a medical home
- Provide case management and care management
- Provide health outreach using neighborhood health workers
- Provide transportation
- Expand capacity (including telehealth and after-hours service)
- Provide direct patient care services

Hospital Readmissions Reduction Program (Sec. 3025, 10309)

The PPACA seeks to reduce Medicare expenditures for patients who have been potentially unnecessarily readmitted to a hospital within a short time after a hospital discharge by reducing hospital Medicare payments for certain excess readmissions. MedPAC has estimated that, in 2005, 17.6% of discharged hospital patients were readmitted within 30 days, accounting for \$15 billion in Medicare spending. Under the PPACA, Medicare payment reductions for IPPS hospitals would begin with FY 2012 for excess readmissions of patients with three applicable conditions involving high volume or high expenditure readmissions – acute myocardial infarction, heart failure, and pneumonia. Beginning with FY 2015, the Secretary is authorized to expand the number of applicable conditions to include chronic obstructive pulmonary disease, coronary artery bypass graft, percutaneous transluminal coronary angioplasty and other vascular conditions, as well as other appropriate conditions and procedures.

The PPACA utilizes a complex formula to determine the amount of the payment reduction for these excess readmissions. Generally, the reduced payment will be determined by applying an "adjustment factor" to the otherwise applicable DRG payment amount (excluding any DSH, IME or low volume components of this amount). The adjustment factor is 1 minus the ratio of the hospital's aggregate payments for excess readmissions to its aggregate payments for all discharges, but is subject to floors of 0.99, 0.98 and 0.97 in fiscal years 2013, 2014 and 2015 and thereafter, respectively. To determine a hospital's aggregate payments for excess readmissions, the formula uses an "excess readmissions ratio" for each applicable condition, which is the ratio (not less than 1.0) of the risk adjusted actual readmissions to the risk adjusted expected readmissions, as determined consistent with a methodology that has been endorsed by a consensus-based organization. Thus, for each applicable condition, the amount of a hospital's payment reduction for its excess readmissions will increase as the proportion of the hospital's excess readmissions increase.

Excess readmissions include only those admissions that occur within a time period (to be specified by the Secretary) following the date of a hospital discharge, and do not include those readmissions that are unrelated to the prior discharge, such as a planned readmission or a

transfer to another hospital. Special rules apply for certain classes of hospitals, including sole community hospitals, Medicare dependent hospitals, and acute care hospitals in Maryland reimbursed under a waiver.

The PPACA directs the Secretary to make readmission rate information derived through this process available to the public on the Hospital Compare website after hospitals have had the opportunity to review and correct such information. In addition, the Secretary is directed to calculate the readmission rates for all patients treated on an inpatient bases and discharged from any acute care or other hospital, including IRFs, inpatient psychiatric facilities, and LTCHs. Hospitals must submit data necessary for the Secretary to calculate such readmission rates (although a state or other appropriate entity may submit the information on behalf of a hospital rather than each hospital submitting such information individually). The Secretary is directed to post information on all-patient readmission rates on the CMS Hospital Compare website. A deadline for this component of the program is not established.

Finally, within two years of enactment, the Secretary must establish a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations (PSOs). Eligible hospitals are those with a high rate of risk adjusted readmissions that have not taken appropriate steps to reduce and improve patient safety. The hospitals and PSOs must report to the Secretary on processes used to improve readmission rates and the resulting impact on readmission rates.

Community-Based Care Transitions Program (Sec. 3026)

The PPACA provides \$500 million to the Secretary to establish a Community-Based Care Transitions Program, which will provide funding to certain hospitals (with high readmission rates) and community-based organizations that furnish improved care transition services to high-risk Medicare beneficiaries. The program will start January 1, 2011 and will last five years, but the Secretary can expand the duration and scope of the program if such expansion will reduce spending without sacrificing quality of care.

The Secretary will establish the application process, but applications are required to include a detailed proposal for at least one care transition intervention, other than discharge planning. In selecting entities to participate in the program, the Secretary must give priority to entities that participate in a program administered by the Administration on Aging, or provide services to medically underserved populations, small communities and rural areas.

Extension of Gainsharing Demonstration (Sec. 3027)

The PPACA extends through September 30, 2011, the three-year gainsharing demonstration project, which had expired December 31, 2009, that was included in the Deficit Reduction Act of 2005. The demonstration project involves arrangements between a hospital and physicians under which the hospital provides for payments to the physicians for savings incurred through

Subtitle B—Improving Medicare for Patients and Providers

Part I—Ensuring Beneficiary Access to Physician Care and Other Services

Geographic Adjustment under the Medicare Physician Fee Schedule (Sec. 3102, Reconciliation Act Sec. 1108)

The PPACA extends a floor on the Geographic Practice Cost Index (GPCI) to work portion of the Medicare Physicians Schedule through 2010, thereby increasing practitioner fees in certain rural areas. The law, as amended by the Reconciliation Act, also establishes a new method to calculate the practice expense GPCI beginning in 2010 to reflect a 50-50 blend of the costs of employee wages and rents in the different fee schedule areas and the national averages. A hold-harmless clause is included to prevent a negative impact from the adjustment. The PPACA also directs the Secretary to analyze methods to fairly and reliably establish distinctions between the costs of operating a medical practice in different fee schedule areas. Based on this analysis, the Secretary must make appropriate adjustments by January 1, 2012, to ensure accurate geographic adjustments across fee schedule areas.

Extension of Exceptions Process for Medicare Therapy Caps (Sec. 3103)

By way of background, the Balanced Budget Act of 1997 (BBA) established two types of annual per-beneficiary limitations on outpatient therapy services: (1) a \$1,500 cap for all outpatient physical therapy (PT) services and speech language pathology (SLP) services; and (2) a \$1,500 cap for all outpatient occupational therapy (OT) services, with both of these amounts indexed for inflation. In 2010, the cap amount is \$1860 for PT and SLP services combined, and \$1860 for OT services.

The DRA required CMS to implement an exceptions process for therapy expenses incurred in 2006. Under this process, a Medicare enrollee (or person acting on behalf of the enrollee) could request an exception from the therapy caps, and the individual could obtain an exception if the provision of services was determined medically necessary (CMS established an automatic process to facilitate exceptions). Congress has since extended this exception process several times; most recently, H.R. 4691, the Temporary Extension Act of 2010, extended the outpatient therapy cap exception process through March 31, 2010. The PPACA further extends the outpatient therapy exception process through December 31, 2010.

Extension of Certain Payment Rules for Long-Term Care Hospital Services and of Moratorium on the Establishment of Certain Hospitals and Facilities (Sec. 3106, 10312)

The PPACA includes a two-year extension to relief granted by section 114(d) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) from the "25% Rule" payment adjustment, the one-time budget neutrality adjustment, and the very short stay outlier payment adjustment. The moratorium in section 114(d) of MMSEA on new LTCHs and satellite facilities, and on the increase of hospital beds in existing LTCHs, is also extended by two years.

Exemption of Certain Pharmacies from DMEPOS Accreditation Requirements (Sec. 3109)

MIPPA established a statutory requirement that Medicare durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers be accredited as meeting certain quality standards in order to furnish DMEPOS items and services on or after October 1, 2009 (with limited exceptions for certain health care professionals).²⁰

The PPACA exempts all pharmacies from the DMEPOS accreditation requirements until January 1, 2011. Moreover, with respect to DMEPOS items furnished on or after January 1, 2011, the PPACA exempts certain pharmacies from the DMEPOS accreditation requirements until such time as the Secretary develops an "alternative accreditation requirement" that is "more appropriate" for such pharmacies. In order to qualify for this provision, the pharmacy must: have billings for such DMEPOS items totaling less than 5% of total pharmacy sales²¹; have been enrolled as a DMEPOS supplier for at least five years; have had no final adverse action for the past five years; submit to the Secretary an attestation (in the manner specified by the Secretary) that it meets the alternative accreditation criteria; and agree to submit materials requested by the Secretary to verify that the criteria are met (including a certification by an accountant or submission of tax returns). Note that this provision does not affect the requirement for pharmacies to be accredited as a condition of participating in the DMEPOS competitive bidding program.²²

Treatment of Certain Complex Diagnostic Laboratory Tests (Sec. 3113)

The PPACA establishes a demonstration program to test the impact of direct Medicare Part B payment to laboratories (including a hospital-based or independent laboratory) for certain complex diagnostic laboratory tests for which the specimen is collected when the individual is a hospital patient, but the test is performed after the hospitalization. Tests that may be included in the demonstration are an analysis of gene protein expression, a topographic genotyping, or a cancer chemotherapy sensitivity assay for which the Secretary determines there is not an alternative test with equivalent performance characteristics, and which is not billed using a "not otherwise classified" code. The two-year demonstration is to begin July 1, 2011, and payments under the demonstration are limited to \$100 million. The Secretary must report to Congress on the outcome of the demonstration and any related recommendations within two years of completion of the demonstration.

²⁰ For additional information on DMEPOS accreditation requirements, see http://www.cms.hhs.gov/MedicareProviderSupEnroll/DMEPOS_DeemedAccreditationOrganizations.asp.

²¹ The level of total pharmacy sales would be determined based on average total pharmacy sales for the previous three CYs, three FYs, or other yearly period specified by the Secretary.

²² For more information on the DMEPOS competitive bidding program, see <http://www.healthindustrywashingtonwatch.com/tags/dmepos-competitive-bidding/>.

Other Medicare Improvements

Among other things, the PPACA:

- Extends through 2010 a provision allowing certain independent laboratories to bill directly for the technical component of certain physician pathology services provided to hospitals. (Sec. 3104)
- Extends Medicare bonus payments established under MIPPA for ground and air ambulance services in rural and other areas through the end of 2010. (Sec. 3105, 10311)
- Extends the MIPPA provision providing a 5% Medicare physician fee schedule add-on payment for certain mental health services through December 31, 2010. (Sec. 3107)
- Authorizes physician assistants to order Medicare post-hospital extended care services, effective January 1, 2011. (Sec. 3108)
- Establishes a Part B special enrollment period for disabled TRICARE beneficiaries. (Sec. 3110)
- Increases Medicare payment for dual-energy x-ray absorptiometry (DXA) services furnished during 2010 and 2011 to 70% of the rate paid in 2006, and requires an Institute of Medicine (IOM) study on the ramifications of Medicare payment for DXA services on Medicare beneficiary access to bone mass density tests. (Sec. 3111)
- Eliminates the remaining funding (approximately \$20.7 billion) under the Medicare Improvement Fund, which was created to finance improvements in Part A and Part B benefits. (Sec. 3112)
- Increases the payment rate for covered services provided by certified nurse midwives from 65% to 100% of the rate that would be paid if a physician were performing the service, effective for services furnished on or after January 1, 2011. (Sec. 3114)
- Provides Medicare coverage and medical screening services to individuals exposed to certain environmental health hazards. (Sec. 10323)
- Requires the GAO to study and report to Congress on whether including certain oral drugs furnished for treatment of end stage renal disease (ESRD) in the upcoming bundled ESRD PPS will impact Medicare beneficiary access to high-quality dialysis services.²³ (Sec. 10336)

Part II—Rural Protections

Extension of Outpatient Hold Harmless Provision (Sec. 3121)

The PPACA extends the Outpatient Hold Harmless Provision of 42 U.S.C. § 1395l(t)(7)(D)(i) to December 31, 2010 and permits sole community hospitals to be eligible for this provision, without regard to the 100-bed limitation.

²³ For more information on the ESRD PPS rulemaking, see <http://www.healthindustrywashingtonwatch.com/2009/09/articles/regulatory-developments/hhs-developments/other-cms-developments/medicare-esrd-pps-proposed-rule/>.

Extension of Medicare Reasonable Cost Payments for Certain Clinical Diagnostic Laboratory Tests Furnished to Hospital Patients in Certain Rural Areas (Sec. 3122)

Section 416(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a program allowing for reasonable cost payments for certain clinical diagnostic laboratory tests furnished by hospitals in certain rural areas. This provision was amended by the Tax Relief and Health Care Act of 2006 and the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), and is currently re-established by the PPACA for one year beginning July 1, 2010.

Extension of the Rural Community Hospital Demonstration Program (Sec. 3123, 10313)

The MMA established a Rural Community Hospital Demonstration Program. The PPACA extends this program for an additional five years. Additionally, during the extension period, the Secretary is instructed to expand the number of eligible states to 20, and expand the number of participating rural community hospitals from 15 to 30. The PPACA also adjusts the funding of hospitals already enrolled in the demonstration program to accommodate the five-year extension.

The PPACA makes technical amendments to the provisions in the MMA governing this demonstration program.

Extension of the Medicare-Dependent Hospital (MDH) Program (Sec. 3124)

The PPACA extends key provisions of the MDH program by one year. Dates governing the program are extended to October 1, 2012, or through FY 2012, as appropriate.

Temporary Improvements to the Medicare Inpatient Hospital Payment Adjustment for Low-Volume Hospitals (Sec. 3125, 10314)

The PPACA modifies the requirements for eligibility as a "low-volume" hospital for FYs 2011 and 2012, including allowing a hospital to be considered "low-volume" if it has 1,600 discharges of individuals entitled to, or enrolled for, Part A benefits, or is located more than 15 miles from another low-volume hospital. Additionally, the PPACA implements a temporary percentage increase in payments for certain qualifying hospitals using a sliding scale for FYs 2011 and 2012.

Improvements to the Demonstration Project on Community Health Integration Models in Certain Rural Counties (Sec. 3126)

The PPACA expands the demonstration project on community health integration models in certain rural counties that was implemented by MIPPA. The PPACA removes the limitation on the number of eligible counties selected for the project, which was originally capped at six, and includes physicians' services in the scope of the project.

MedPAC Study on Adequacy of Medicare Payments for Health Care Providers Serving in Rural Areas (Sec. 3127)

The PPACA requires the Medicare Payment Advisory Commission (MedPAC) to conduct a study on the payments for suppliers and providers serving rural areas under the Medicare program, including access by rural Medicare beneficiaries to services, payments to rural providers and suppliers, and the quality of care in rural areas. By January 1, 2011, MedPAC must submit a report to Congress with the result of the study, including suggestions for adjusting payments to rural providers and suppliers, and with suggestions for additional legislative or administrative action.

Technical Correction Related to Critical Access Hospital Services (Sec. 3128)

The PPACA makes two technical corrections to the provision governing payment for outpatient critical access hospital services. Under 42 U.S.C. § 1395m(g)(2)(A), a critical access hospital may elect to be paid for outpatient critical access hospital services, including a facility fee. PPACA sets the fee at 101% of the reasonable costs of the critical access hospital in providing such services. Additionally, under § 1395m(l)(8), the provision governing the establishment of a fee schedule for ambulance services, the ambulance services furnished to critical access hospitals are now payable at 101% of the reasonable costs incurred, subject to the provisions of that subsection.

Extension of and Revisions to Medicare Rural Hospital Flexibility Program (Sec. 3129)

The PPACA amends the Rural Health Flexibility Program outlined in 42 U.S.C. § 1395i-4(j) by extending the program to allow for appropriations for the program from the Federal Hospital Insurance Trust Fund in 2011 and 2012 to remain available until expended. These changes apply to grants made on or after January 1, 2010. The PPACA also makes a technical correction to this subsection.

The PPACA expands the awarding of grants to hospitals for upgrading data systems and the use of those funds, per 42 U.S.C. § 1395i-4(g)(3). Now, grants may be awarded for assisting hospitals in participating in delivery system reforms that are part of the PPACA, including value-based purchasing programs, accountable care organizations, and other delivery system reform programs. In addition to the uses outlined in this section, a hospital may use these grant funds to participate in the delivery system reforms made by the PPACA. The PPACA also includes a technical correction to this subsection.

Part III—Improving Payment Accuracy

Payment Adjustments for Home Health Care (Sec. 3131, 3401, 10315)

HHAs are paid under a prospective payment system based upon 60-day episodes of care, subject to certain adjustments. The payment levels are determined by grouping patients into

Home Health Resource Groups based upon a patient assessment, subject to certain adjustments. Outlier payments are made for extraordinarily high-cost patients. Payment rates are updated annually each calendar year (CY) based upon a projected market basket index for home health services. In recent years, HHAs have had Medicare payment reductions to address what CMS believes are increases in case-mix that are related to coding rather than actual severity of patient illness. MedPAC has also found that HHA payment rates have exceeded costs since the prospective payment system was adopted, and it recommended no annual increase in 2010 and rebasing to reflect more accurately the average cost of care.

The PPACA follows this trend and these recommendations, reducing the market basket update by 1 percentage point for CYs 2011 through 2013. The Secretary is also directed to impose a productivity adjustment on payment rates, beginning in 2015. The law expressly notes that application of adjustments may lead to market basket increases of less than zero, and payment rates for one year less than the preceding year. Further, beginning in 2014, the PPACA directs the Secretary to rebase home health payments by a percentage amount based on an analysis of the current mix of services and intensity of care provided to home health patients. The Secretary is specifically authorized to consider differences between HHAs regarding hospital-based and free-standing providers, for profit and nonprofit providers, and resource costs for urban and rural providers. The adjustments will be phased in over four years, with adjustments being fully implemented by 2017. Payment reductions will be limited to 3.5% annually.

The law also establishes a 10% cap on the amount of outlier payments each HHA can receive, and reinstates a 3% add-on payment for rural home health providers beginning April 1, 2010 through 2015. In addition, the law requires the Secretary to submit a plan to Congress no later than October 1, 2011, to include HHAs into a Medicare value-based purchasing program, as for other providers under PPACA.

Finally, the law directs the Secretary to study improving access to home health care for certain patients, including those with high-severity levels of illness and who are low-income and living in underserved areas, and to report to Congress by March 1, 2014 on the study and with recommendations for legislation and administrative action. The law also authorizes the Secretary to conduct a demonstration program to determine whether making adjustments for Medicare home health services would substantially improve access to care for high-severity patients or for low-income or underserved Medicare beneficiaries.

Hospice Payment Reforms (Sec. 3132)

PPACA requires the Secretary to collect hospice data by not later than January 1, 2011, in preparation for revising hospice payments. Such data can include charges, payments, numbers of days of hospice care by service level, levels of charitable contributions to hospices, number and types of visits, and the like. Based on this information, the Secretary is required no earlier than FY 2013 to "implement revisions to the methodology for determining the payment rates for

routine home care and other services included in hospice care." Such revisions can include adjustments to per diem payments "that reflect changes in resource intensity in providing such care and services during the course of the entire episode of hospice care." The payment revisions must in any event result in the same aggregate expenditures for hospice care as for the prior FY.

After January 1, 2011, a hospice physician or nurse practitioner must (1) have a face-to-face encounter with each hospice patient prior to the 180th-day recertification and each subsequent recertification, in order to determine continued eligibility for hospice care, and (2) attest that such visit took place. In addition, the Secretary must establish procedures for medical review of patients whose stays exceed 180 days, in hospices with a certain percentage (to be determined by the Secretary) of long-stay patients.

Improvement to Medicare DSH Payments (Sec. 3133, 10316, Reconciliation Act Sec. 1104, 1109)

The PPACA, as amended by the Reconciliation Act, substantially reduces Medicare DSH payments to hospitals beginning in FY 2014 by reducing the DSH payment to 25% of the amount to which the hospital would be entitled under the Medicare DSH statute. The PPACA also provides that the Secretary will pay an additional amount to DSH-eligible hospitals for uncompensated care, beginning in FY 2015, equal to the product of the following factors or based on an alternative factor determined by the Secretary:

- Factor 1: the difference between the aggregate amount of payments that would be made to DSH-eligible hospitals under the Medicare DSH statute in the absence of the new PPACA amendment (section 3133 of PPACA) and the aggregate amount of payments that are made to DSH-eligible hospitals under section 3133;
- Factor 2: 1 minus the percentage change in the number of uninsured individuals under 65 years of age (the percentage change in uninsured individuals being determined by comparing the number of patients insured in 2013 with the number of individuals insured during the most recent period for which data is available);
- Factor 3: the percent, for each DSH-eligible hospital, represented by the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary, and the aggregate amount of uncompensated care for all DSH-eligible hospitals. There is no administrative or judicial review of the Secretary's estimates used to determine the three factors comprising the calculation of the uncompensated care payment outlined in this section.

The Reconciliation Act also provides an additional payment under Medicare PPS for hospitals located in counties in the bottom quartile of counties as ranked by risk-adjusted spending per Medicare beneficiary.

Misvalued Codes under the Physician Fee Schedule (Sec. 3134)

The PPACA directs the Secretary to periodically identify and adjust relative value units (RVU) for physician fee schedule services that may be misvalued. In particular, the Secretary is required to examine codes and families of codes that have experienced the fastest growth or substantial changes in practice expense; codes that represent new technologies or service; multiple codes that are frequently billed in conjunction with furnishing a single service; codes associated with low relative values; and codes that have not been subject to review since the implementation of the resource-based relative value scale (RBRVS). The PPACA sets forth a number of methods the Secretary may use to identify and analyze such services. As part of this process, the Secretary also is authorized to make appropriate coding revisions, which may include consolidation of individual services into bundled codes for payment under the Medicare physician fee schedule. In addition, the PPACA requires the Secretary to establish a process to validate RVUs under the physician fee schedule, including a validation of the work elements involved with furnishing a service. The validation process is required to include a sampling of codes identified in the review of potentially misvalued codes. The Secretary is directed to make adjustments to the work RVUs as appropriate. The Secretary would be authorized to implement these new provisions by program instruction or otherwise.

The PPACA also repeals the statutory authority for the Practicing Physicians Advisory Council (in a provision entitled "Focusing CMS Resources on Potentially Overvalued Codes"). Additionally, the PPACA repeals a Balanced Budget Act of 1997 requirement that the Secretary develop new resource-based practice expense RVUs.

Modifications of Equipment Utilization Factor for Advanced Imaging Services (Sec. 3135, Reconciliation Act Sec. 1107)

Historically, CMS assumed that imaging equipment was used 25 hours per week (50% of the time) in applying practice expense RVS values to payments for imaging services. If this utilization factor were increased, the cost of the equipment (and thus the payments) would spread over more units of service, thus lowering the payments-per-procedure for the imaging service. The 2010 Medicare Physician Fee Schedule final rule had adopted a 90% utilization rate for certain imaging equipment valued at more than \$1 million that CMS stated included CT and MR services, with the 90% rate to be phased in over a 4-year period. The PPACA adopted a 4-year phased-in increase of the utilization rate with an eventual 75% utilization rate for advanced imaging (defined as CT, MR, nuclear medicine and PET), phased in as follows: 65% in 2010-2012, 70% in 2013, and 75% in 2014. The Reconciliation Act amended the PPACA's standard. Under the final policy, the PPACA, as amended by the Reconciliation Act, adopts a 75% utilization rate, effective 2011, applicable to equipment as defined in the 2010 Medicare Physician Fee Schedule final rule, that is for imaging equipment priced at \$1 million or more (CT and MR).

The PPACA also increases the discount for the technical component of additional imaging studies performed on the same Medicare patient, the same day, from 25% to 50%.

Revision of Payment for Power-Driven Wheelchairs (Sec. 3136)

The PPACA eliminates the lump-sum payment option for power-driven wheelchairs, although the lump-sum payment option is maintained for complex, rehabilitative power wheelchairs. The PPACA also modifies rental payment amounts for power-driven wheelchairs. Specifically, payment is set at 15% (rather than 10%) of the purchase price for each of the first three months, and at 6% (rather than 7.5%) of the purchase price for each of the remaining 10 months. These provisions are effective for power-driven wheelchairs furnished on or after January 1, 2011, except that they will not apply to payment made for items and services furnished under DMEPOS competitive bidding contracts entered into prior to January 1, 2011.

Other Medicare Studies and Demonstrations

The PPACA includes a number of other demonstrations and studies, such as the following:

- An HHS study of whether existing IPPS-exempt cancer hospitals have costs under the outpatient PPS (OPPS) that exceed costs of other hospitals, including costs associated with drugs and biologicals, and to make an appropriate payment adjustment under OPPS based on that analysis, effective for services furnished on or after January 1, 2011. (Sec. 3138)
- The Secretary must study the need for additional Medicare payments for certain urban Medicare-dependent hospitals paid under the Medicare IPPS. (Sec. 3142)
- The Secretary is authorized to establish a demonstration program to "provide financial incentives to Medicare beneficiaries who are furnished services by high quality physicians." The provision specifies that Medicare beneficiaries may not be required to pay increased premiums or cost sharing, or be subject to a reduction in Medicare benefits as a result of the demonstration. The Secretary also must ensure that any such demonstration program does not disadvantage beneficiaries without reasonable access to high-performing physicians or create financial inequities under Medicare. (Sec. 10331)

Payment for Biosimilar Biological Products (Sec. 3139)

The PPACA amends section 1847A of the Social Security Act (42 U.S.C. § 1395w-3a) (average sales price methodology) by adding a new subparagraph C that provides that Medicare Part B payment for a "biosimilar" biologic product is the average sales price plus 6% of the "reference" or brand biological product. A biosimilar biological product is defined as "a biological product approved under an abbreviated application for a License of a biological product that relies in part on data or information in an application for another [licensed] biological product...." The payment provisions apply on the "first day of the second calendar quarter after enactment of legislation providing for a biosimilar pathway (as determined by the Secretary)."

Medicare Hospice Concurrent Care Demonstration Program (Sec. 3140)

The Secretary is directed to establish a three-year demonstration program that would allow patients who are eligible for hospice care also to receive all other Medicare-covered services while receiving hospice care, using funds that otherwise would be paid to hospice programs. The demonstration will be conducted in up to 15 hospice programs in both rural and urban areas and will undergo an independent evaluation of its impact on patient care, quality of life and "cost-effectiveness for Medicare beneficiaries."

Hospital Wage Index Provisions (Sec. 3141, 10324, 10317)

Beginning in 2009, the Secretary changed the way that each state's "rural floor" hospital wage index was calculated, from being budget neutral on a national basis to being budget neutral on a statewide basis. The change was scheduled to be phased in over several years. The PPACA reverses the 2009 policy, changing the effectuation of budget neutrality back to a nationwide approach.

Section 10324 of the PPACA further ensures that hospitals located in "frontier" states (defined as a state in which 50% of the counties have less than six people per square mile) will not have an area wage index of less than 1. The adjustment does not apply to states where hospitals receive an adjustment to their non-labor related share. The provision is not subject to budget neutrality.

In addition, section 10317 extends reclassifications under section 508 of the MMA through the end of FY 2010, and requires the Secretary to provide recommendations to Congress on ways to comprehensively reform the Medicare wage index system by December 31, 2011. This provision also directs the Secretary to restore the reclassification thresholds used to determine hospital reclassifications to the percentages used in FY 2009, starting in FY 2011 until the first FY that is on or after the date the Secretary submits the report to Congress on reforming the wage index system. Section 10317 also clarifies that the Secretary may only use wage data of certain eligible hospitals in carrying out this provision if doing so does not result in lower wage index adjustments for affected facilities.

Protecting Home Health Benefits (Sec. 3143)

Notwithstanding all of the HHA payment adjustments in PPACA, which the legislation clearly states could constitute payment cuts, the PPACA expressly provides that nothing in the law "shall result in the reduction of guaranteed home health benefits" under the Medicare program. There are widespread questions as to whether providers will be able to reduce costs as much as contemplated by the legislation.²⁴ This provision could prove useful in the future if HHAs find

²⁴ See <http://src.senate.gov/files/OACTMemorandumonFinancialImpactofPPAA%28HR3590%29%2812-10-09%29.pdf#page=33>. According to Senate Republicans, the OACT did not have time to analyze the Reconciliation Act prior to Congressional consideration (see

that the Medicare payment cuts under the PPACA reduce their ability to provide home health benefits to Medicare beneficiaries.

Revision to Skilled Nursing Facility Prospective Payment System (Sec. 10325)

Under Medicare, SNFs are paid under a PPS that provides payment on a per diem basis based upon the acuity level and care needs of the beneficiary. The payment levels are determined by grouping patients into payment-adjusted Resource Utilization Groups (RUGs) based upon a patient assessment known as the Minimum Data Set (MDS). Payment rates are updated annually each federal FY based generally upon the consumer price market basket index. For several years, SNFs received the full market basket increase in payment rates. However, for FY 2010, which began October 1, 2009, payments to SNFs were reduced by 1.1%. While the payment levels reflect a 2.2% market basket inflation update, that amount was more than offset by a 3.3% adjustment intended to recalibrate case-mix weights to compensate for increased expenditures resulting from refinements made in January 2006.

As part of the FY 2010 SNF payment rule, CMS announced a revised case-mix classification methodology (RUG-IV) to be implemented for FY 2011, which begins October 1, 2010. CMS also adopted several payment changes that were intended to more accurately reflect the cost of caring for Medicare beneficiaries as determined by the recently completed Staff Time and Resource Intensity Verification (STRIVE) project. These include release of an updated MDS known as MDS 3.0. In addition, CMS changed treatment of concurrent therapy (one professional therapist treating multiple patients at the same time, each of whom is receiving different therapy) to require the time (minutes) spent to be allocated among the patients receiving therapy rather than as individual therapy minutes for purposes of recording minutes on the MDS. CMS also eliminated the "look-back" period under which SNFs could reflect on the MDS certain treatments while the patient was in the hospital prior to admission to the SNF to indicate the patient's acuity level for purposes of case-mix classification.

Unlike for some other Medicare providers, the PPACA makes no reductions to the market basket update for SNFs in FY 2010 or FY 2011. Further, the law delays implementation of the RUG IV system for one year until FY 2012, which begins October 1, 2011. However, the law does *not* delay implementation of the changes to the concurrent therapy rules or the look-back period, or launch of the new MDS 3.0, which will go into effect October 1, 2010.

Subtitle C—Provisions Relating to Part C

Medicare Advantage (Medicare Part C)

PPACA, as amended by the Reconciliation Act, modifies the Medicare Advantage program in some significant ways. Adjustments to payments for Medicare Advantage Organizations (MAOs) are phased in over time, penalties may apply if medical loss ratios fall below 85%, and there are several new quality initiatives, including a rating system that will drive the amount of the beneficiary rebate, as well as payment incentives for plans. Other changes apply to special needs plans, election periods for beneficiaries, and the elimination of the Stabilization Fund.

Payments to Medicare Advantage Organizations (Reconciliation Act Sec. 1102)

Modifications to payments to MAOs are found primarily in the Reconciliation Act. They include:

- **Payment Benchmarks.** Since 2006, the calculation for payments to Medicare Advantage Organizations have been calculated based upon a plan's bid as compared with a benchmark estimate of costs. Thus, these benchmarks are a central part of the payment to Medicare Advantage Organizations. The Reconciliation Act establishes a blended benchmark that is phased in over time, taking into account the phase-out of indirect medical education costs from the capitation rate. The benchmark for 2011 will be held equal to that of 2010. In 2012 and later, an adjusted blended benchmark (set forth in the Reconciliation Act) will apply. Area-specific benchmark amounts used in the calculation of capitation payments range from 95% for areas ranked in the highest cost quartile to 115% for areas in the lowest quartile. Modifications are, in general, phased in over three years; for areas in which the benchmark adjustments exceed \$30 per member per month, the phase-in time frame may be extended.
- **Quality Rating to Affect Payment Incentives.** The Reconciliation Act directs the Secretary to create a "5-star rating system" of Medicare Advantage health plans. This rating system allows for an MAO to receive an increase in capitation, at either a plan or contract level. This quality rating is to be determined based on data collected from the plans. Incentive payment percentages range from 1.5% in 2012 to 5% in 2014, with the Secretary having discretion to apply them.

Benefit Protection and Simplification (Reconciliation Act Sec. 1102(d))

An MAO is required to share with enrollees any savings it achieves between the benchmark and its contract bid. Previously, the rebate percentage was 75% of the savings; the Reconciliation Act states that, beginning in 2012, the percentage will vary based on the star rating. The level of rebate now ranges from 50 to 70% of the savings.

Coding Intensity Adjustment (Reconciliation Act Sec. 1102(e))

The Reconciliation Act continues to apply a "coding intensity adjustment" that adjusts capitation rates to reflect changes in treatment and coding practices occurring at the fee-for-service level until the Secretary implements risk adjustment mechanisms using diagnostic, cost and use data collected from MAOs.

Repeal of Comparative Cost Adjustment Program (Reconciliation Act Sec. 1102(f))

The Reconciliation Act repeals the Comparative Cost Adjustment Program, which was a program that provided for an alternative calculation of capitation payments for certain geographic areas.

Limits on Medicare Advantage Plan Administrative Costs (Reconciliation Act Sec. 1103)

Beginning in 2014, the Reconciliation Act requires that Medicare Advantage plans have a medical loss ratio of at least 85%; if a plan's medical loss ratio falls below this level, the difference must be returned to the Secretary. Plans that fall below 85% for three consecutive contract years will not be permitted to enroll new members for the second succeeding contract year, and plans that fall below this level for 5 consecutive years will have their contracts terminated.

Beneficiary Election Periods (Sec. 3204)

PPACA changes the time frame within which Medicare beneficiaries can opt out of the Medicare Advantage program and return to receiving coverage under Medicare Parts A and B. Beginning in 2011, enrollees will be permitted to disenroll from their Medicare Advantage plan and resume coverage under the original Medicare fee-for-service plan within the first 45 days of the year. Previously, beneficiaries had an open enrollment period of three months within which to make this election. The timing of the annual election period for Medicare Advantage will also change; beginning in 2012, the period will begin about one month earlier and end about three weeks earlier.

Extending Specialized Medicare Advantage Plans for Special Needs Individuals (Sec. 3205)

PPACA includes several amendments to the program for Medicare Advantage Special Needs Plans (MA-SNP). Enrollment, payment, service area, and quality standards for plans are each modified. These changes include:

- **Restrictions on Enrollment.** PPACA extends the ability of these plans to restrict enrollment to only individuals who meet the criteria for special needs individuals. This provision, which was previously in place until January 1, 2011, is now extended until January 1, 2014. PPACA directs the Secretary to develop transition procedures for individuals who are currently enrolled in an MA-SNP plan but who are not considered special needs individuals.

- **Adjustment to Payments**
 - *Frail Populations.* PPACA modifies the way in which MA-SNPs may be paid. Beginning in 2011, the Act allows for a "frailty adjustment" to the payment levels for MA-SNPs that enroll special needs individuals who have "similar average levels of frailty as the PACE program" and are entitled to Medicaid. Beginning in 2011, these plans may be paid under the rules that are applicable to the PACE program (rather than using the revised payment schedule set forth in the Reconciliation Act); this exception will apply as long as the plan is "fully integrated with capitated contracts" for Medicaid benefits, including long-term care.
 - *Chronic Conditions.* Also beginning in 2011, a separate risk adjustment will be put in place for special needs individuals who have multiple, comorbid chronic health conditions and individuals with a diagnosis of mental illness. This revised risk adjustment will be evaluated periodically to establish an accurate risk adjustment.
- **Service Area Expansion Restrictions Continued.** The restriction on service area expansion for MA-SNPs, introduced in the MIPPA, was extended for an additional two years, until December 31, 2012.
- **Quality Control.** PPACA confers on the Secretary the authority, beginning in 2012, to require MA-SNPs to obtain approval by the National Committee for Quality Assurance.

Extension of Reasonable Cost Contracts (Sec. 3206)

In cases where an insufficient number of health plans are offered in a region and/or there are insufficient enrollees to allow for a risk contract to be practicable, the Medicare Advantage program allows for managed care services to be reimbursed on a reasonable cost contract basis. A statutory requirement is currently in place that after January 1, 2010, no extension or renewal of a cost contract may occur if two or more separately owned MAOs offer plans in the area. PPACA extends the January 1, 2010 deadline by three years, until January 1, 2013.

Medicare Advantage Senior Housing Facility Plans (Sec. 3208)

Medicare Advantage Senior Housing Facility Plans enrolling individuals residing in a continuing care retirement community that were participating in a demonstration project for at least one year will, beginning for plan years on or after January 1, 2010, be allowed to continue offering the plan permanently. The service area of these types of plans may be limited to a senior housing facility in a geographic area.

Authority to Deny Plan Bids (Sec. 3209)

Beginning on or after January 1, 2011, the Secretary has the authority to deny contract bids that propose significant increases in cost sharing or decreases in benefits.

Development of New Standards for Certain Medigap Plans (Sec. 3210)

PPACA requires a revision by the National Association of Insurance Commissioners of the standards for group plan Medigap insurance benefit packages. The revision is stated to serve the purpose of updating standards "to include requirements for nominal cost sharing to encourage the use of appropriate physicians' services under Part B."

Elimination of the Medicare Advantage Stabilization Fund (Sec. 10327)

The Medicare Advantage Stabilization Fund was designed to provide incentives to have an MA plan offered in each region and to retain plans in certain MA regions that had market penetration at less than the national average. Originally established by the Medicare Prescription Drug Improvement and Modernization Act in 2003, the fund has received consistent reductions by subsequent legislation, including the Tax Relief and Healthcare Act of 2006, the Medicare, Medicaid and SCHIP Extension Act of 2007, and the MIPPA. PPACA finalizes this trend by eliminating the fund entirely. Any funds remaining will be transferred to the Federal Supplementary Medical Insurance Trust Fund.

Subtitle D—Medicare Part D Improvements for Prescription Drug Plans and MA–PD Plans

Medicare Coverage Gap ("Donut Hole") Discount Program (Sec. 3301)

By way of background, the Medicare Part D prescription drug benefit structure, created pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA), includes a gap in coverage that this new provision addresses in part, beginning in 2011. Specifically, under the "standard" Part D benefit, coverage of prescription drugs extends until the beneficiary hits an "initial coverage limit" of covered Part D drug costs (in 2010, this is \$2,830); after that point, the beneficiary has no coverage (technically, 100% co-insurance, referred to as the "coverage gap" or "donut hole") until he or she incurs (or is deemed to have incurred) out-of-pocket costs for covered Part D drugs equal to an out-of-pocket maximum (in 2010, this is \$4,450). At that point, the "catastrophic" portion of the Part D benefit structure kicks in, and beneficiaries are required to pay only small copays (e.g., in 2010, \$2.50 for generics and \$6.30 for branded drugs, subject to some exceptions).

The PPACA requires that, beginning January 1, 2011, manufacturers of "applicable drugs" provide a discount equal to 50% of the "negotiated price" of such drugs when dispensed to "applicable beneficiaries" during the coverage gap. "Applicable drugs" generally refers to branded drugs and biological products that are on the given Part D plan's formulary; specifically, the definition includes covered Part D drugs "approved under a new drug application [NDA] under Section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (PHSA) (other than a product licensed under subsection (k) of such section)," which are either on the plan's formulary or for which coverage has been granted to the beneficiary through an exception or appeal.

These discounts do not extend to generic drugs, except, presumably, for "authorized generics," which are "generic" versions of drugs manufactured under an NDA.

"Applicable beneficiary" is defined as an individual Part D plan enrollee who is not entitled to low-income subsidies (LIS beneficiaries). "Negotiated price" refers to the price that the beneficiary would otherwise pay for the given drug at the given pharmacy during the coverage gap, other than any dispensing fee; in practice, this generally refers to the price negotiated between the Part D plan sponsor and the pharmacy for the given drug (excluding the dispensing fee).

Manufacturers of applicable drugs are required to agree to provide these discounts during the coverage gap or donut hole in order to have any of their drugs eligible for coverage under Medicare Part D, subject to an exception where the Secretary "has made a determination that the availability of the drug is essential to the health of" Part D beneficiaries, or to the extent that the Secretary determines that, during 2011, there were "extenuating circumstances." While it is not clear what the Secretary might require to grant such exceptions, the language suggests that unique drugs or biologics (e.g., cancer drugs for which there are no therapeutic alternatives) could be excepted from the mandatory discount requirement.

The Secretary is required to establish a form of agreement for manufacturers to agree to provide the coverage gap discounts not later than 180 days after the enactment of this section, and manufacturers must enter into such agreements within 30 days thereafter (per amendments made in the Reconciliation Act). The Secretary is also required to enter into a contract with a third-party to administer this "Medicare coverage gap program." It appears that funds are to flow from manufacturers through this third-party contractor to pharmacies, to reimburse them for providing these discounts at the point of sale, with pharmacies entitled to be paid within 14 days for claims submitted electronically, and within 30 days for claims submitted otherwise. This could present a significant operational challenge, since there are no existing mechanisms for transmitting claims information from pharmacies or Part D plan sponsors to such a third-party contractor, or for such contractor to pay such funds to pharmacies. In light of these issues, the legislation includes certain exceptions for CY 2011. Specifically, if it is not practicable to provide discounted prices at the point of sale during 2011, the Secretary may establish procedures to provide such discounts as soon as practicable after the point of sale, and while the Secretary is prohibited from receiving manufacturers' funds, this prohibition does not apply for 2011 if the Secretary determines an exception is necessary in order to begin implementation and provide beneficiaries timely access to the discounts. Part D plan sponsors are required to provide appropriate data to the Secretary for administration of the program.

Importantly, the provision revises the definition of "incurred costs" under Part D, for purposes of determining the point at which a beneficiary has passed through the coverage gap and is eligible for catastrophic coverage. "Incurred costs" now include the entire negotiated price of an applicable drug dispensed to an applicable beneficiary during the coverage gap, regardless of

the fact that part of the cost is paid by the manufacturer; however, when the coverage gap starts shrinking in 2011 (see next section), the portion of the negotiated price paid by the Part D plan sponsor pursuant to the revised "standard" Part D benefit does not count toward "incurred costs." This feature was part of the agreement negotiated by the Pharmaceutical Research and Manufacturers of America (PhRMA) during the days when health reform was being formulated early in 2009, and means that manufacturer funding of these discounts will help to move beneficiaries through the coverage gap to the Part D catastrophic benefit.

Notably, because of the way the term "incurred costs" has been redefined, it appears that there may be significantly greater potential for Part D plan sponsors to offer "supplemental" or "enhanced" Part D benefit plans with more added coverage of branded drugs in the coverage gap. This is because it appears that payments by the Part D plan sponsor for those drugs in the coverage gap as a supplemental benefit to "standard" Part D coverage will now count as "incurred costs" by the beneficiary, meaning the beneficiary will move through the gap as fast as if the beneficiary had paid such costs himself or herself.²⁵ Under prior law, enhanced benefit coverage of branded drugs in the coverage gap has been rare, since the beneficiary would not exit the gap until he or she incurred the required level of out-of-pocket costs; when drugs were covered in the coverage gap, the beneficiary's out-of-pocket costs were reduced, thereby pushing back the level of total drug costs necessary to exit the gap. Additionally, the plan is required to charge an additional premium for the actuarial value of drugs covered in the gap. The new law could reduce the economic disadvantages that such plans have faced.

This provision also adds a new exception to the federal anti-kickback statute at 42 U.S.C. § 1320a-7b(b)(3), to expressly provide that the new manufacturer discounts will not constitute a violation of that statute; this effectively overrules the 2005 HHS Office of Inspector General (OIG) ruling that manufacturer assistance to beneficiaries during the coverage gap could constitute a violation of that statute.²⁶

²⁵ The PPACA provided that "incurred costs shall include the negotiated price...of an applicable drug...of a manufacturer that is furnished to an applicable beneficiary...under the Medicare coverage gap discount program...regardless of whether part of such costs were paid by a manufacturer under such program." The Reconciliation Act added to this language an exclusion of amounts paid by the Part D plan pursuant to the changes to the "standard" Part D benefit, but that language does not appear to encompass supplemental benefits. This could result in CMS having to apportion drug costs covered by an enhanced benefit Part D plan during the coverage gap between "standard" benefit costs (which will not count as incurred) and "enhanced" benefit costs (which would)—which could prove to be a challenging administrative task, and difficult to explain to beneficiaries. It is possible that CMS will attempt to construe the statutory language as providing only that the 50% manufacturer discounts will count as "incurred" to avoid these issues.

²⁶ "Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees," 70 FR 70623 (Nov. 22, 2005).

Closing the Medicare Prescription Drug Benefit Coverage Gap ('Donut Hole') (Reconciliation Act Sec. 1101)

This provision provides a \$250 payment to Part D beneficiaries who reach the coverage gap during 2010, and also provides for the gradual elimination of the coverage gap, beginning in 2011 and finishing in 2020.

Specifically, any Part D plan enrollee who, as of the end of a calendar quarter during 2010, has "incurred" costs for covered Part D drugs in excess of the initial coverage limit (\$2,830), shall be paid \$250 by the Secretary by the 15th day of the third month following the end of such calendar quarter. Notably, such payment is to be made regardless of whether the beneficiary in fact incurs \$250 in covered Part D drug costs in the coverage gap.

The provision closes the coverage gap beginning in 2011 by gradually reducing the Part D "standard" benefit coinsurance percentage that beneficiaries pay during the gap to 25%, which is the same coinsurance percentage as applies prior to the gap.²⁷ The legislation does this separately for "applicable drugs" (as such term is defined for purposes of the Medicare Coverage Gap Discount Program), i.e., branded drugs and biologics, and for covered Part D drugs other than "applicable drugs" (i.e., generics). The coinsurance percentages during the coverage gap for applicable and generic drugs are shown below; please note that, since 50% of the negotiated price of applicable drugs is being picked up by the manufacturer pursuant to the Medicare Coverage Gap Discount Program, the government will end up paying only approximately 25% of the cost of those drugs in 2020:

Year	Applicable Drug Coinsurance	Generic Drug Coinsurance
2010	100%	100%
2011	50%*	93%
2012	50%*	86%
2013	47.5%	79%
2014	47.5%	72%
2015	45%	65%
2016	45%	58%
2017	40%	51%
2018	35%	44%
2019	30%	37%
2020	25%	25%

²⁷ In lieu of 25% coinsurance, the vast majority of Part D plans use actuarially equivalent copay tiers for different drugs; e.g., \$10 for generics, \$30 for preferred brands and \$50 for non-preferred brands. The law as revised would also permit such actuarially-equivalent tiering in lieu of a single coinsurance percentage during the coverage gap, and we would expect most plans to adopt that approach.

*The statutory language does not include a coinsurance percentage for 2011 or 2012; we have assumed this means coinsurance would remain at 100%, less the 50% manufacturer discount. Note that this will not be exactly 50% coinsurance, since the beneficiary must pay the entire dispensing fee in addition to 50% of the drug cost.

Additionally, the Reconciliation Act changes the inflation indexing used to calculate the out-of-pocket limit that defines the upper end of the coverage gap, i.e., the point at which the beneficiary exits the coverage gap and catastrophic coverage applies. Under the MMA, the out-of-pocket limit was to be adjusted upward each year by the percentage increase in average per capita expenditures for covered Part D drugs in the United States for Part D eligible individuals (referred to by CMS as the "average percentage increase"); based upon such indexing, the out-of-pocket threshold has increased from \$3,600 in 2006 to \$4,550 in 2010. Under the new legislation, for each of 2014 and 2015, the adjustment will be the amount of the average percentage increase less 0.25%. For each of 2016 through 2019, the adjustment will be the lesser of (1) the average percentage increase, or (2) the annual percentage increase in the consumer price index for all urban consumers, plus 2%. In 2020, the out-of-pocket limit will be set as though these amendments had not been enacted.

Improvement in Determination of Medicare Part D Low-Income Benchmark Premium; Voluntary "de minimis" Policy for Subsidy-Eligible Individuals under Prescription Drug Plans and Medicare Advantage Prescription Drug (MA-PD) Plans (Sec. 3302, 3303)

Under current law, Medicare Part D beneficiaries who are "dually eligible" under Medicare and their state Medicaid program pay no premium for their Part D coverage so long as they are enrolled in a Part D plan whose beneficiary premium is at or below the "benchmark" premium in the given prescription drug plan (PDP) region. The "benchmark" premium is essentially the weighted average premium for Part D plans in the given PDP region.

Effective January 1, 2011, the benchmark premium will be determined without regard to any premium reductions for MA-PD Part D plans because of a refund or bonus associated with the medical benefit under the associated MA plan. In the past, MA plan refunds have resulted in some MA-PDs having a zero premium. This will have the effect of raising the benchmark premiums, resulting in more Part D plans falling below the benchmark thresholds.

Additionally, Part D plans whose premium is above the benchmark premium by a "de minimis" amount will be permitted to waive that excess for low-income subsidy-eligible Part D beneficiaries. "De minimis" is not defined, and presumably will be defined by the Secretary; in the past the Secretary operated a demonstration program that used \$2 or \$1 as a de minimis amount. This will permit plans waiving that portion of their premium to avoid having their dually eligible enrollees reassigned to other Part D plans, and appears to also permit these plans to receive assignment of new dually eligible enrollees.

Special Rule for Widows and Widowers Regarding Eligibility for Low-Income Assistance (Sec. 3304)

This provision will extend the effective period of low-income subsidy (LIS) status for a Part D LIS enrollee whose spouse dies, by one year. Accordingly, beneficiaries whose income and resources are low enough to qualify them for a given LIS status when measured against the criteria for a married couple will not lose LIS status when measured against the criteria for single individuals, for a period of one year.

Improved Information for Subsidy Eligible Individuals Reassigned to Prescription Drug Plans and MA-PD Plans (Sec. 3305)

This section requires the Secretary to provide, to those LIS enrollees who are reassigned by the Secretary to a different Part D plan, information on the formulary differences between the old and new plans, and a description of the enrollee's right to request an exception to the new formulary, which may include a request for coverage on a lower cost-sharing tier.

Funding Outreach and Assistance for Low-Income Programs (Sec. 3306)

This section provides additional amounts to fund low-income outreach and assistance by state health insurance programs, area agencies on aging, and similar entities, through 2012. Additionally, the Secretary may request that such entities conduct outreach activities aimed at preventing disease and promoting wellness, and such use of funds by the entities is permitted.

Improving Formulary Requirements for Prescription Drug Plans and MA-PD Plans with Respect to Certain Categories or Classes of Drugs (Sec. 3307)

Through operational guidance, since the beginning of the Part D program in 2006, the Secretary has established six categories of drugs as meriting special formulary treatment. Stated differently, Part D sponsors have been required to include all drugs (or a generic equivalent) in these six categories on their formularies. These classes were anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals and immunosuppressants. MIPPA required that the Secretary establish categories and classes of drugs for which such formulary treatment would be required, specifying criteria for such determinations—e.g., whether "restricted access to drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class." The Secretary has engaged in a process to make such determinations for future years though it is not clear whether this would result in additions and/or subtractions to the current six classes to which such treatment has been extended so far.

The PPACA has replaced the MIPPA provision with language that removes the criteria specified by MIPPA, and instead allows the Secretary to establish these categories and classes using "criteria established by" the Secretary. The Secretary is to establish any such criteria, and

any exceptions to the requirement that all drugs in the class be on formulary, through a rulemaking that includes a public notice and comment period. Until such determinations are made, the existing six classes are to be accorded such status.

Reducing Part D Premium Subsidy for High-Income Beneficiaries (Sec. 3308)

Beginning in 2011, Part D enrollees who have "modified adjusted gross income" in excess of specified levels (\$85,000 in 2010 for a beneficiary filing an individual income tax return or married and filing a separate return, and \$170,000 for a beneficiary filing a joint tax return), will have their Part D premiums adjusted upward. "Modified adjusted gross income" is defined for such purposes as adjusted gross income under the Internal Revenue Code, determined without regard to sections 135, 911, 931 and 933 of the Code.

The amount of the increase is determined pursuant to a formula; while difficult to understand, it appears that monthly premiums could more than double for some of the beneficiaries subject to these adjustments, with smaller increases for others.

These income-related increases in Part D premiums are to be paid through withholding from Social Security checks.

Elimination of Cost Sharing for Certain Dual-Eligible Individuals (Sec. 3309)

Part D beneficiaries receiving both Medicare and Medicaid benefits are relieved from paying cost sharing (e.g., deductibles, copays, and coinsurance in the prescription drug coverage gap) for covered Part D drugs if they are "institutionalized." This term is currently defined to refer to beneficiaries in nursing facilities and certain other medical facilities. This provision will expand such treatment to beneficiaries who would be institutionalized if they were not receiving services outside of such a facility pursuant to a home and community-based waiver pursuant to a section 1115 Medicaid waiver, a state plan amendment, or through enrollment in a Medicaid managed care organization.

This provision is to be effective when specified by the Secretary, but no sooner than January 1, 2012.

Reducing Wasteful Dispensing of Outpatient Prescription Drugs in Long-Term Care Facilities under Prescription Drug Plans and MA-PD Plans (Sec. 3310)

This provision requires the Secretary to require Part D plan sponsors to "utilize specific, uniform dispensing techniques" as determined by the Secretary, "such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills."

The provision goes into effect in 2012. The Secretary is to consult with relevant stakeholders, including nursing facility representatives and residents, pharmacists, retail and long-term care pharmacies, Part D plans and others determined appropriate by the Secretary, in determining what techniques it will require.

Improved Medicare Prescription Drug Plan and MA-PD Plan Complaint System (Sec. 3311)

The Secretary is required to develop and maintain a complaint system, "that is widely known and easy to use," to collect and maintain information on Part D plan complaints received by the Secretary through the date the complaint is resolved. The system must be able to "report and initiate appropriate interventions and monitoring based on substantial complaints and to guide quality improvement."

The Secretary must promulgate a model electronic complaint form to be used in connection with this system, and the form must be prominently displayed on the front page of the Medicare.gov website, and on the Internet website of the Medicare Beneficiary Ombudsman.

This section does not specify an effective date; as such, it appears to be effective immediately.

Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans (Sec. 3312)

Effective January 1, 2012, Part D plan sponsors are required to use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) for determining prescription drug coverage for their Part D enrollees. They must also provide "instant access to such process through a toll-free telephone number and an internet website."

Office of the Inspector General (OIG) Studies and Reports (Sec. 3313)

The OIG is required to prepare and deliver reports on the following:

- Part D plan formularies' inclusion of drugs commonly used by dual eligibles, to be delivered to Congress annually, by July 1 of each year (beginning with 2011).
- Prescription drug prices under Part D and Medicaid, including a comparison, for the 200 most frequently dispensed drugs, of the prices (taking into account rebates) paid by Part D plans and state Medicaid programs. Notwithstanding any other provision of law, the OIG shall be able to collect any information related to such prices necessary to carry out such comparison. The report is to be submitted to Congress by October 1, 2011, but shall not include proprietary information or information that OIG determines is likely to negatively impact the ability of Part D plan sponsors to negotiate prices.

Including Costs Incurred by AIDS Drug Assistance Programs and Indian Health Service in Providing Prescription Drugs toward 'Incurred Costs' Threshold under Part D (Sec. 3314)

Effective January 1, 2011, Part D drug costs paid by a state pharmaceutical assistance program, the Indian Health Service, an Indian tribe or tribal organization, an urban Indian organization, or an AIDS drug assistance program will be treated as "incurred" by the beneficiary for purposes of the annual out-of-pocket threshold. As such, beneficiaries of such programs will move out of the coverage gap and into the catastrophic coverage portion of the Part D benefit more quickly.

Improvement in Part D Medication Therapy Management (MTM) Programs (Sec. 10328)

Under the MMA, Part D plan sponsors are required to conduct MTM programs for "targeted beneficiaries," defined as those who have multiple chronic diseases, are taking multiple covered Part D drugs, and are expected to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary. In the MMA, Congress did not impose specific requirements for MTM programs; CMS has established these through operational guidance, initially leaving the content of such programs largely up to Part D plan sponsors, and more recently imposing more specific requirements.

Beginning in 2013, Part D plan sponsors will be required to offer targeted beneficiaries an annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or "other qualified provider."

The review "may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent practicable," and shall include providing the individual with a written summary of the results of the review. The Secretary, in consultation with relevant stakeholders, is required to develop a standardized format for the action plan.

The MTM program is also required to include "[f]ollow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies...."

Part D plan sponsors are required to have in place "a process to assess, on at least a quarterly basis, the medication use of individuals who are at risk but not enrolled" in the MTM program, including beneficiaries who have experienced a transition in care, if they have access to that information.

Part D plan sponsors must also have a process for automatically enrolling targeted individuals and individuals identified at risk in the MTM program, and to permit such beneficiaries to opt-out of such program.

Subtitle E—Ensuring Medicare Sustainability

Revision of Market Basket Updates, Incorporation of Additional Productivity Adjustments (Sec. 3401, 10319, and Reconciliation Act Sec. 1105)

The market basket component of the Medicare physician fee schedule update mechanism – the Medicare economic index -- already is adjusted to exclude productivity gains. The PPACA implements a longstanding recommendation of MedPAC that Medicare market basket updates for other providers be adjusted to reflect productivity gains in delivering health care services and to

encourage more efficient care.²⁸ In essence, this is a rate cut. Specifically, the PPACA incorporates a productivity adjustment to market basket updates for: inpatient hospitals, inpatient psychiatric facilities, LTCHs, IRFs, HHAs, SNFs, hospice providers, ASCs, dialysis facilities, and certain Part B providers and suppliers. For each provider type, the productivity offset equals a 10-year average of a statistic that is published by the Department of Labor Statistics, specifically, the "percentage change in the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity" ²⁹ (as projected by the Secretary for the applicable 10-year period). It is important to note that because the productivity offset is equal to a 10-year moving average, it will change year-to-year. The Bureau of Labor Statistics reports the annual non-farm, multi-factor productivity in the spring of each year. Using the average change in the applicable productivity measures from 1999-2008, the offset percentage would be approximately 1.3%.³⁰ As detailed below, the effective dates of the adjustment vary. Moreover, certain providers are subject to additional market basket reductions beyond the annual productivity adjustment – which could result in a provider experiencing a negative update (i.e., a rate cut) (except as otherwise noted). The following is a summary of the PPACA's provider-specific market basket updates, incorporating a number of revisions made by the Reconciliation Act:

- **Acute Care Hospitals and IRFs.** For acute care hospitals reimbursed under the IPPS and for IRFs, the PPACA establishes a full productivity adjustment beginning in FY 2012. In addition, as amended by the Reconciliation Act, the market basket update for such facilities is reduced: by 0.25 percentage points in FY 2010 and FY 2011; by 0.1 in FY 2012 and FY 2013; by 0.3 in FY 2014; by 0.2 in FY 2015 and FY 2016; and by 0.75 in FY 2017 through FY 2019. Subsection 3401(p) provides that these amendments will not apply to discharges occurring before April 1, 2010.
- **LTCHs.** LTCHs will be subject to a full productivity adjustment beginning in rate year (RY) 2012. In addition, as amended by the Reconciliation Act, the LTCH market basket

²⁸ The CMS Office of the Actuary (OACT) issued its analysis of H.R. 3590 December 10, 2009. As with OACT's analysis of the earlier House health reform bill, the report charges that the savings associated with annual productivity adjustments for most providers are probably "unrealistic" since it is doubtful most providers could reduce costs to the extent envisioned in the legislation.

²⁹ The Bureau of Labor Statistics defines multi-factor productivity (MFP) as follows: "MFP measures reflect output per unit of a set of combined inputs. A change in MFP reflects the change in output that cannot be accounted for by the change in combined inputs. As a result, MFP measures reflect the joint effects of many factors including research and development (R&D), new technologies, economies of scale, managerial skill, and changes in the organization of production." In addition, the Bureau of Labor Statistics explains that productivity measurement is important because "Advances in productivity, that is the ability to produce more with the same or less input, are a significant source of increased potential national income. In the long run, increases in real hourly earnings are tied to productivity gains. The U.S. economy has been able to produce more goods and services over time, not by requiring a proportional increase of labor time, but by making production more efficient." Bureau of Labor Statistics, Frequently Asked Questions (July 30, 2008) at <http://www.bls.gov/mfp/mprfaq.htm#Q02>.

³⁰ This calculation is based on numbers published by the Bureau of Labor Statistics and available on its website at www.bls.gov.

- update is reduced: by 0.25 percentage points in RY 2010; by 0.5 in RY 2011; by 0.1 in RY 2012 and RY 2013; by 0.3 in RY 2014; by 0.2 in RY 2015 and RY 2016; and by 0.75 in RY 2017 through RY 2019. Subsection 3401(p) provides that these amendments will not apply to discharges occurring before April 1, 2010.
- **Outpatient Hospitals.** The PPACA establishes a full productivity adjustment for outpatient hospital services beginning in CY 2012. In addition, as amended by the Reconciliation Act, the PPACA reduces the market basket update for outpatient hospital services by 0.25 percentage points in 2010 and 2011; by 0.1 in 2012 and 2013; by 0.3 in 2014; by 0.2 in 2015 and 2016; and by 0.75 in 2017 through 2019.
 - **Psychiatric Hospitals.** Psychiatric hospitals will be subject to a full productivity adjustment beginning in RY 2012. In addition, as amended by the Reconciliation Act, the market basket update for such facilities is reduced: by 0.25 percentage points in RY 2010 and FY 2011; by 0.1 in RY 2012 and RY 2013; by 0.3 in RY 2014; by 0.2 in RY 2015 and RY 2016; and by 0.75 in RY 2017 through RY 2019.
 - **Skilled Nursing Facilities.** The SNF market basket update will be subject to a full productivity adjustment beginning in FY 2012.
 - **Home Health Agencies.** The PPACA imposes a productivity adjustment on HHAs beginning in CY 2015. In addition, the HHA market basket update is reduced by 1 percentage point in 2011 through 2013.
 - **Hospice Care.** Beginning in FY 2013, Medicare payments for hospice services will be subject to a productivity adjustment. Further, for FYs 2013 to 2019, hospice payments will be subject a market basket reduction of 0.3%; however, the reductions in FYs 2014 through 2019 will be waived if a designated threshold for reductions in the uninsured population is not achieved.
 - **Dialysis Facilities.** The PPACA deletes the 1 percentage point reduction in the end stage renal disease (ESRD) market basket update that was scheduled to take effect beginning in 2012. Instead, the PPACA establishes a full productivity adjustment to the ESRD market basket update, beginning in 2012.
 - **ASC and Ambulance Services.** The update for ASC services and ambulance services will be subject to a productivity adjustment starting in CY 2011.
 - **Laboratory services.** The PPACA retains the existing 0.5 percentage point reduction to the inflation update for laboratory services for CY 2009 and 2010, and it establishes a 1.75 percentage point reduction to the update in CY 2011 through 2015. It also establishes a productivity adjustment for clinical laboratory services beginning in 2011. While the 1.75% reduction may result in the update for a year being less than 0%, the productivity adjustment will not apply in a year when the adjustment otherwise would be 0% or less, nor can it result in the fee schedule being reduced below 0%.
 - **Durable Medical Equipment.** The PPACA eliminates the full inflation update to the DME fee schedule for 2011 through 2014, in addition to a 2% add-on scheduled to be applied in 2014 to those items that had been selected for inclusion in the first round of the DMEPOS competitive bidding program and that had been subject to a 9.5% fee

schedule reduction in 2009. Instead, for 2011 and each subsequent year, DME rates will be increased by the rate of increase in the CPI-U less the productivity adjustment.

- **Prosthetic Devices, Orthotics, Prosthetics, Medical Supplies, and Other Items.** Beginning in CY 2011, the PPACA applies a productivity adjustment factor to the inflation update for prosthetic devices, orthotics, and prosthetics, and to the update for any fee schedule established for medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine.

Temporary Adjustment to the Calculation of Part B Premiums (Sec. 3402)

Under the Medicare Modernization Act, certain higher-income beneficiaries have been subject to income-based Part B premiums, with threshold amounts updated annually by changes in the CPI. The PPACA freezes the income thresholds at 2010 levels through 2019.

Independent Payment Advisory Board (Sec. 3403, 10320)

In a controversial provision that could have significant long-term impact on Medicare provider payments, the PPACA establishes an Independent Payment Advisory Board (IPAB) to develop and submit detailed proposals to Congress and the president to reduce Medicare per-capita spending when projected spending growth exceeds a target. In contrast to the recommendations of the current MedPAC, whose recommendations are purely advisory, the IPAB's proposals will go into effect automatically unless Congress enacts specific legislation with alternative provisions to achieve the required level of savings (with certain exceptions).³¹ Such legislation would be considered under complex "fast track" parliamentary procedures.

The 15-member IPAB will be appointed by the president and confirmed by the Senate. Membership will include nationally recognized experts in fields such as health finance and economics, integrated delivery systems, and health facility management, along with physicians and other providers. All members must meet ethics disclosure and conflict of interest standards, and a majority of the IPAB must be comprised of members who are *not* directly involved with the provision or management of the delivery of items and services under Medicare.

The IPAB's first proposal with savings recommendations could be submitted by January 14, 2014, for implementation in 2015, if the Medicare per capita target growth rate is exceeded. For 2014 through 2017, this target rate is based on a comparison of the projected rate of growth in

³¹ Note that in addition to the binding recommendations triggered by specific spending growth levels, the IPAB is authorized to submit nonbinding recommendations for years with lower growth rates. The Board also is authorized to submit non-binding recommendations to Congress and the president on ways to slow the growth in national, non-federal health care spending.

Medicare spending per beneficiary compared with the average of the increase in the CPI-U and CPI for medical care (CPI-M); in subsequent years proposals will be required only when the projected rate of growth in Medicare spending exceeds the increase in the per capita GDP plus 1%. Any required IPAB proposals must achieve specified levels of savings, ranging from the lesser of (1) 0.5% to 1.5%, and (2) the amount by which Medicare spending exceeds the trigger.

With regard to the Medicare payment reduction options the IPAB can consider, the PPACA prohibits the board from making proposals that ration care, raise taxes or Part B premiums, or change Medicare standards for benefits, eligibility, or cost-sharing. The IPAB also is precluded from submitting proposals that reduce Medicare payments prior to December 31, 2019, for providers scheduled to receive a reduction in their payment updates in excess of a reduction because of productivity.³² As appropriate, each proposal must include recommendations to reduce spending in Medicare Parts C and D, such as reductions in direct subsidy payments for administrative expenses, denial of high bids for drug coverage from national average monthly bid calculations, and reductions in MA performance bonuses. The IPAB also is directed, as feasible, to: (1) prioritize recommendations that would extend Medicare solvency; (2) include recommendations that improve the health care delivery system and health outcomes (such as by promoting integrated care, care coordination, prevention and wellness efforts, and quality and efficiency improvement), and protect beneficiary access to "necessary and evidence-based items and services," including in rural and frontier areas; (3) target reductions to sources of excess Medicare cost growth; (4) consider the effects on Medicare beneficiaries of changes in provider and supplier payments; (5) consider the effects of proposals on providers with actual or projected negative profit margins or payment updates; (6) consider the unique needs of individuals dually eligible for Medicare and Medicaid; and (7) consider the IPAB's findings on system-wide health care costs, access, and quality in developing proposals that effectively promote the delivery of efficient, high-quality care to Medicare beneficiaries. Any such proposals may not increase Medicare spending over the initial 10-year period.

It is too early to predict the scope of spending reductions that will be achieved through adoption of the IPAB's proposals, or the extent to which Congress will act to substitute its own savings plans for those of the IPAB. The Congressional Budget Office (CBO) expects this provision to yield savings of about \$28 billion over the period of 2015 to 2019.³³ The CMS Office of the Actuary (OACT) predicted that most of the savings from this provision would be generated as a result in reductions in payments to physicians, hospitals, MA plans, and Part D drug plans.³⁴

³² For more information on productivity adjustments, see discussion *supra* regarding section 3401.

³³ See <http://www.cbo.gov/doc.cfm?index=10868&type=1>, page 11.

³⁴ See <http://src.senate.gov/files/OACTMemorandumonFinancialImpactofPPAA%28HR3590%29%2812-10-09%29.pdf#page=33>, page 10.

Subtitle F—Health Care Quality Improvements

Quality Improvement (Sec. 3501)

The PPACA requires the Agency for Healthcare Research and Quality (AHRQ), through its Center for Quality Improvement and Patient Safety (the Center), to engage in 10 specific quality improvement activities, including, among other things, identifying best practices for improving quality in health care delivery. The PPACA also requires the Center to support research on ways to improve the health care delivery system and tools to facilitate the adoption of best practices that would improve health care quality, safety, and efficiency. Such research must meet specific requirements enumerated in the PPACA, and research findings must be made available to the public and shared with the Office of the National Coordinator of Health Information Technology. The Center is also required under the PPACA to coordinate its activities with the new Center for Medicare and Medicaid Innovation. The PPACA appropriates \$20 million through 2014 for these functions.

The Center must award grants for both "technical assistance" and "implementation" of best practices identified through the Center's research functions. The PPACA sets forth eligibility criteria for each type of grant and requires prospective recipients of such grants to follow an application procedure. An entity must have "demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement" to be eligible for either a "technical assistance" or an "implementation" grant. Recipients of these grants must agree to contribute matching funds toward the technical assistance and implementation activities to be performed.

Community Health Teams and Patient-Centered Medical Homes (Sec. 3502)

The PPACA requires the Secretary to establish a program to make grants to or enter into contracts with states that will be used to create, "health teams." These, in turn, contract with primary care providers meeting certain criteria to provide primary care support services. Among other things, health teams must:

- Include an interdisciplinary, interprofessional team of health care providers that may include, among other things, specialists, nurses, pharmacists, nutritionists, social workers, and mental health providers
- Support "patient-centered medical homes" defined as a "mode of care that includes—(A) personal physicians; (B) whole person orientation; (C) coordinated and integrated care; (D) safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements; (E) expanded access to care; and (F) payment that recognizes added value from additional components of patient-centered care," with priority given to individuals amenable to prevention and those with chronic disease conditions

- Collaborate with local primary care providers to coordinate disease prevention, chronic disease management, transitioning between health care settings, and case management
- Demonstrate the "capacity to implement and maintain health information technology . . . to facilitate coordination among the members of the health team and affiliated primary care practices"
- Provide other support necessary for primary care providers to improve quality of care

Recipients of grants or contracts under this section must have a plan for achieving long-term financial sustainability within three years, and are required to report to the Secretary on the various activities performed by the health teams.

Medication Management Services in Treatment of Chronic Disease (Sec. 3503)

The PPACA requires the Secretary (through the Patient Safety Research Center) to begin establishing a program by May 1, 2010 to make grants to or enter into contracts with entities that will be used to implement medication management services for "targeted individuals" (defined as individuals who take four or more prescribed medications, take any "high-risk" medications, have two or more chronic diseases, or otherwise have a high risk for medication-related problems). Among other things, such medication management services must include: an appropriate patient assessment; an individualized medication treatment plan; patient monitoring; a comprehensive medication review to identify, resolve, and prevent medication-related problems; and patient/caregiver education and training. The PPACA requires the Secretary to consult with experts, including private entities, academic institutions, professional organizations, and other stakeholders, in "designing and implementing" its medication management services program.

Regionalized Emergency Care (Sec. 3504)

The PPACA requires the Secretary (through the Assistant Secretary for Preparedness and Response) to award at least four "multiyear contracts or competitive grants" to state and/or local governments in support of pilot projects that "design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems." Pilot projects must follow certain application procedures and must meet certain criteria to be eligible for a grant, including, among other things, that they ensure patients are taken to the medically appropriate facility within the given region and maintain a region-wide data management system. Recipients of the contracts or grants must agree to contribute matching funds toward the regionalized emergency care pilot projects and must report the results of the pilot project to the Secretary, who will make such results available to the public and to Congress as appropriate. The PPACA requires the Secretary to give priority to prospective recipients in medically underserved areas.

The PPACA further appropriates "such sums as may be necessary" through FY 2014 to the Secretary in support of emergency medical research, including pediatric emergency medical research.

Trauma Care (Sec. 3505)

With respect to trauma care, the PPACA requires the Secretary to directly award grants (not to exceed \$2 million per grant for each FY) to public, nonprofit trauma centers to (1) defray their substantial uncompensated care costs; (2) further their core missions; and (3) provide emergency relief to ensure future availability of trauma centers. The PPACA establishes categories of eligible trauma centers based on their percentage of uncompensated care, and specifies criteria for award amounts.

The PPACA further requires the Secretary to make funds available to states so that states can award grants to eligible trauma centers in order to promote "universal access to trauma care services and trauma-related physician specialties." Congress appropriated \$100 million per year from 2010 through 2015 for purposes of grants to states for promotion of trauma service availability.

Shared Decision Making (Sec. 3506)

By way of background, pursuant to MIPPA, HHS awarded a contract to the National Quality Forum (NQF) in 2009 to help establish a portfolio of quality and efficiency measures that would enable the government to analyze whether health care spending is achieving the best results for patients and taxpayers. The PPACA requires the Secretary to award NQF another contract to: (1) support "preference sensitive care" (defined as medical care for which "clinical evidence does not clearly support 1 treatment option," and therefore must be based on patient values, preferences, and the risks and benefits associated with treatment alternatives according to current scientific evidence); and (2) establish consensus-based standards and a certification process for patient "decision aids" (defined as an "educational tool" to assist patients and caregivers with making "preference sensitive care" decisions). The PPACA also requires the Secretary to provide grants to establish "Shared Decisionmaking Resource Centers" and to encourage health care providers to participate in training offered by the Shared Decisionmaking Resource Centers (or comparable training), and implement shared decision-making techniques using certified "decision aids."

Prescription Drug Benefit and Risk Information (Sec. 3507)

The PPACA requires FDA to determine whether adding quantitative risk/benefit summaries to drug labeling (including promotional materials) in a standardized format, such as a "table" or "drug facts box," would improve clinicians' and consumers' health care decision making. FDA must report its determination to Congress within one year and, to the extent FDA determines such summaries would improve health care decision making, implement its determination through proposed regulations within three years of its report to Congress.

Clinical Education of Health Professionals Demonstration Project—Quality Improvement and Patient Safety Training (Sec. 3508)

The PPACA authorizes the Secretary to award grants on a competitive basis to eligible schools or institutions in order to fund demonstration projects for developing and implementing quality improvement and patient safety training into health professionals' clinical education, provided the recipient agrees to contribute matching funds.

Improving Women's Health (Sec. 3609)

The PPACA establishes five new offices to focus on issues of particular concern to women's health:

- Within HHS's Office of the Secretary, the Office on Women's Health
- Within the Centers for Disease Control and Prevention's (CDC's) Office of the Director, the Office of Women's Health
- Within AHRQ's Office of the Director, the Office of Women's Health and Gender-Based Research
- Within the Health Resources and Services Administration's (HRSA) Office of the Administrator, the Office of Women's Health
- Within FDA's Office of the Commissioner, the Office of Women's Health

In addition, the Substance Abuse and Mental Health Services Administration (SAMHSA), which already has an Associate Administrator for Women's Services (who, under the PPACA, will report directly to SAMHSA's Administrator), is authorized to establish an Office of Women's Health. The PPACA requires the HHS Office on Women's Health to establish a "Coordinating Committee on Women's Health" and a "National Women's Health Information Center" to promote the exchange of information related to women's health issues, and permits it to make grants to carry out its purpose subject to periodic evaluation of projects funded by such grants and the publication of any information developed. The PPACA transfers existing women's health programs and functions within each agency to the new offices where appropriate, and authorizes "such sums as may be necessary" to be appropriated for the new offices to carry out their functions during FYs 2010 through 2014.

Extension of Patient Navigator Demonstration Program Grants (Sec. 3510)

The PPACA repeals the sunset provision applicable to Patient Navigator demonstration program grants established under the Patient Navigator Outreach and Chronic Disease Prevention Act of 2005 (Pub. Law 109-18); imposes minimum core proficiency requirements for individual patient navigators (who are individuals with "direct knowledge of the communities they serve" and are trained to facilitate patient care for individual patients); and authorizes appropriations for Patient Navigator demonstration program grants through 2015.

Minority Health (Sec. 10334)

The PPACA establishes the Office of Minority Health as part of HHS and also establishes a network of minority health offices located within HHS. The Offices of Minority Health will monitor health, health care trends, and quality of care among minority patients and evaluate the success of minority health programs and initiatives. Section 10334 also elevates the National Center on Minority Health and Health Disparities at the National Institutes of Health from a center to an institute.

Subtitle G—Protecting and Improving Guaranteed Medicare Benefits

The PPACA includes language declaring that nothing in the legislation will result in a reduction of Medicare guaranteed benefits, and stating that any savings generated for the Medicare program under the PPACA will be used to extend the solvency of the Medicare trust funds, reduce Medicare premiums and cost-sharing, and improve or expand guaranteed Medicare benefits and protect access to providers. Moreover, the PPACA states that nothing in the legislation will result in the reduction or elimination of any benefits guaranteed by law to MA plan participants.

Notwithstanding this declaration, the impact of the PPACA on the Medicare program – including beneficiaries, providers, and health plans – is the subject of much debate. For instance, the CBO stated in a March 19, 2010 letter to the Ranking Republican on the House Budget Committee that "[i]n effect, the majority of the [Hospital Insurance] trust fund savings under H.R. 3590 and the reconciliation proposal would be used to pay for other spending and therefore would not enhance the ability of the government to pay for future Medicare benefits."³⁵ Likewise, with regard to the impact on beneficiary access to providers, the CMS OACT noted in an analysis of the PPACA (prior to the adoption of a package of amendments) that the savings associated with the legislation's annual productivity adjustments are probably "unrealistic" since it is doubtful most providers could reduce costs to the extent envisioned in the legislation. OACT simulations project that about 20% of Part A providers could become unprofitable within 10 years as a result of the productivity adjustments, which could result in providers ending their participation in Medicare and potentially jeopardizing Medicare beneficiary access to care.³⁶

³⁵ See <http://www.cbo.gov/ftpdocs/113xx/doc11376/RyanLtrhr4872.pdf>

³⁶ See footnotes 24 and 28, above.

Title IV—Prevention of Chronic Disease and Improving Public Health

Subtitle A—Modernizing Disease Prevention and Public Health Systems

National Prevention, Health Promotion and Public Health Council (Sec. 4001)

This provision establishes an interagency National Prevention, Health Promotion and Public Health Council to develop a national health care strategic policy focused on improving the health status of Americans and reducing preventable diseases. An advisory group to the council is also established under this provision.

Prevention and Public Health Fund (Sec. 4002)

This section establishes a Prevention and Public Health Investment Fund to be used to expand and sustain national investment in prevention, wellness, and public health activities authorized by the PHSA, including prevention research and health screenings. The goal of the fund is to improve health and help restrain the rate of growth in private and public sector health care costs.

Clinical and Community Preventive Services (Sec. 4003)

This provision expands the efforts of and improves the coordination between the U.S. Preventive Services Task Force and the Community Preventive Services Task Force, two task forces that provide recommendations relating, respectively, to clinical preventive services and community preventive interventions.

Education and Outreach Campaign Regarding Preventive Benefits (Sec. 4004)

Under this section, the Secretary will establish a national public/private partnership for a prevention and health promotion outreach and education campaign. The goal of this effort is to raise awareness of ways to promote health and prevent disease across a person's lifespan. Activities under the program will include a media campaign, a website that includes a personalized prevention plan tool, outreach to providers, and a public awareness campaign to educate Medicaid enrollees regarding availability and coverage of preventive and obesity-related services.

Subtitle B—Increasing Access to Clinical Preventive Services

School-Based Health Centers (Sec. 4101)

This provision establishes and provides \$50 million yearly in funding from FY 2010 to FY 2013 for a grant program focused on the development of facilities and purchase of equipment for school-based health centers which will provide comprehensive primary health services to medically underserved children.

Oral Healthcare Prevention Activities (Sec. 4102)

This provision establishes a five-year public education campaign that focuses on oral health care education and disease prevention. It also provides for cooperative agreements with states, territories and Indian tribes to improve oral health, sets up a demonstration grant program focused on the effectiveness of research-based "dental caries disease management" activities, and updates and strengthens national oral health care surveillance activities.

Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan (Sec. 4103, Reconciliation Act Sec. 10402).

Beginning in January 2011, this section provides complete coverage under the Medicare program for annual personalized prevention plan services beginning after a beneficiary's initial year of enrollment. These services will include a comprehensive health risk assessment, the establishment of a five- to 10-year screening schedule, development of a listing of risk factors, and personalized health advice and/or health education or preventive counseling. The Secretary is also directed to establish guidelines and models for health risk assessments under this section.

Removal of Barriers to Preventive Services in Medicare (Sec. 4104, Reconciliation Act Sec. 10406)

Pursuant to this section, Medicare will begin to cover the entire cost of most preventive health care services beginning in January 2011. Beneficiary coinsurance requirements and deductibles will be waived for personalized prevention plan services and covered preventive services recommended with a grade of A or B by the U.S. Preventive Services Task Force in all settings.

Evidence-Based Coverage of Preventive Services in Medicare (Sec. 4105)

This section gives the Secretary the authority to modify or eliminate Medicare coverage of any currently covered preventive service if the change is consistent with U.S. Preventive Services Task Force recommendations. Services related to diagnosis and treatment are excluded from this provision.

Improving Access to Preventive Services for Eligible Adults in Medicaid (Sec. 4106)

Effective in January 2013, state Medicaid programs are given the option to provide clinical preventive service recommended with a grade of A or B by the U.S. Preventive Services Task Force, and adult vaccinations recommended by the Advisory Committee on Immunization Practices. States that choose to cover these items and that prohibit beneficiary cost-sharing will receive a 1% increase in the FMAP for these additional services and vaccines.

Coverage of Comprehensive Tobacco Cessation Services for Pregnant Women in Medicaid (Sec. 4107)

Beginning in October 2010, this provision requires states to cover the full cost of diagnostic, therapy, and counseling services, and pharmacotherapy relating to tobacco cessation for pregnant Medicaid recipients.

Incentives for Prevention of Chronic Diseases in Medicaid (Sec. 4108)

This section establishes a five-year, \$100 million grant program for states to provide incentives to Medicaid beneficiaries who successfully participate in programs that advance healthy lifestyle habits, including tobacco cessation, weight control, lowering cholesterol or blood pressure, and avoiding or better managing diabetes. Grants under this program will begin to be awarded beginning no later than January 2011.

Subtitle C—Creating Healthier Communities

Community Transformation Grants (Sec. 4201)

This section establishes a competitive grant program for state and local governments, community organizations, and Indian tribes, which focuses on promoting healthier community lifestyles. The program authorizes funding for FYs 2010 through 2014 for community-oriented preventive health activities, such as creating healthier school environments and work site wellness programs that enhance nutrition, reduce smoking, and increase opportunities for physical activity in order to reduce chronic disease rates, prevent the development of secondary conditions, and address health disparities.

Healthy Aging, Living Well; Evaluation of Community-Based Prevention and Wellness Programs for Medicare Beneficiaries (Sec. 4202)

This provision aims to control chronic disease and reduce Medicare costs by providing grants to state and local governments and Indian tribes to establish five-year pilot programs focused on enhancing the health of the pre-Medicare-eligible 55 to 64 year age group. In addition to community-based public health interventions, preventive screenings and clinical referrals may be provided under the program. Further addition, this provision calls for evaluation of existing community prevention and wellness programs and developing plans to promote such services for Medicare-eligible individuals.

Removing Barriers and Improving Access to Wellness for Individuals with Disabilities (Sec. 4203)

This section requires the establishment of standards that promote access to and usability of medical diagnostic equipment for disabled individuals.

Immunizations (Sec. 4204)

Under this provision, states are authorized to contract directly with manufacturers for the purchase and delivery of adult vaccines, thereby reducing anticipated costs. This section also establishes a demonstration program that provides grants to states to improve immunization coverage among high-risk populations. Finally, the immunization program in section 317 of the PHSA is reauthorized, and a GAO report regarding coverage of and access to vaccines under Medicare Part D is requested under this provision. One million dollars is provided for FY 2010 in otherwise unappropriated funds.

Nutrition Labeling of Standard Menu Items at Chain Restaurants (Sec. 4205)

Restaurant chains of 20 or more locations doing business under the same name and offering substantially the same menu items will be required to provide caloric information on menus and menu boards under this provision. In addition, other nutrition information shall be available in written form upon request by consumers. Certain vending machine operators will also be required to provide caloric information. Proposed regulations to implement these requirements must be promulgated within a year from enactment of this provision.

Demonstration Project Concerning Individualized Wellness Plan (Sec. 4206)

This section establishes a pilot demonstration program with up to 10 community health centers to provide comprehensive risk-factor assessment and individualized wellness planning to at-risk populations who utilize these centers.

Reasonable Break Time for Nursing Mothers (Sec. 4207)

This provision amends the Fair Labor Standard Act to require employers with 50 or more employees to provide nursing mothers with break time and a location to express milk.

Subtitle D—Support for Prevention and Public Health Innovation

Research on Optimizing the Delivery of Public Health Services (Sec. 4301)

Under this section, the CDC is directed to fund research regarding public health services and systems, including examination of prevention practices, analysis of the transition from academia to the real world, and identification of effective strategies for delivering public health services.

Understanding Health Disparities; Data Collection and Analysis (Sec. 4302)

This provision directs federal health programs to collect and report data on race, ethnicity, sex, language, disability status, and other demographic data that may reflect health disparities. This information is to be analyzed by HHS to detect and monitor trends in health disparities, which shall be reported throughout federal agencies and to the public. While funding is authorized, specific federal appropriations for the program are still needed.

CDC and Employer-Based Wellness Programs (Sec. 4303)

This section attempts to expand employer-based wellness by providing employers with technical assistance and other resources, including those to enhance their ability to evaluate such programs. It also directs the CDC to conduct a survey that will assess the benefits of such programs.

Epidemiology-Laboratory Capacity Grants (Sec. 4304)

This provision establishes a grant program under which the CDC will provide funding to public health agencies to improve monitoring of and responses to infectious diseases and other significant conditions affecting public health. For each FY between 2010 and 2013, \$190 million is authorized for this program.

Advancing Research and Treatment for Pain Care Management (Sec. 4305)

Although funding will have to be provided through other legislation, this provision authorizes a conference on pain-related issues in order to increase recognition of pain as a significant public health problem, evaluate the adequacy of existing pain treatment, identify barriers to pain care, and establish a plan to both reduce such barriers and improve research, education and pain-related care in the United States. In addition, the HHS is directed to establish an Interagency Pain Research Coordinating Committee, and the NIH Pain Consortium is encouraged to conduct an aggressive pain-related research program, and is directed to submit annual recommendations on worthy research initiatives. Finally, this provision authorizes a grant program to educate and train health care professionals in assessment, diagnosis, treatment, and management of acute or chronic pain.

Funding for Childhood Obesity Demonstration Project (Sec. 4306)

This provision appropriates \$25 million for the five-year period between FYs 2010 and 2014 for a childhood obesity reduction demonstration project authorized in CHIPRA.

Subtitle E—Miscellaneous Provisions

Effectiveness of Federal Health and Wellness Initiatives (Sec. 4402)

This provision directs the Secretary to evaluate existing federal health and wellness programs, with particular focus on the effectiveness they have had on the federal workforce.

Better Diabetes Care (Sec. 10407)

This section seeks to improve diabetes care by directing the Secretary to prepare a national diabetes report card every two years, analyzing trends in preventive care practices, quality of care, costs, risk factors, prevalence, and outcomes. In addition, the Secretary is directed to educate and train physicians on improved collection and reporting of birth- and death-

certificate data, including diabetes mortality data. Finally, this provision calls for a study on the impact of diabetes on medical care in the United States, and whether enhancements in diabetes medical education are needed.

Grants for Small Businesses to Provide Comprehensive Workplace Wellness Programs (Sec. 10408)

This section establishes a five-year grant program under which small businesses may obtain funding to provide employees with access to comprehensive workplace wellness programs that include initiatives such as education, screenings, health risk assessments, counseling, seminars, and self-help materials. Such programs should also maximize employee participation and foster supportive workplace environments. From FY 2011 to 2015, a total of \$200 million is authorized for this grant program.

Cures Acceleration Network (CAN) (Sec. 10409)

Section 10409 of PPACA requires that NIH establish a CAN within the Office of the Director of NIH. CAN will conduct and support "revolutionary advances" in basic research, and will award grants and contracts, and provide resources necessary to accelerate the development of "high need cures," including through the development of medical products and behavioral therapies. High-need cures are defined as drugs, devices, or biological products that NIH determines are a priority to diagnose, mitigate, prevent or treat harm from a disease or condition, and for which commercial incentives are unlikely to result in adequate or timely development. In addition to awarding grants and contracts to accelerate development of high-need cures, CAN will reduce barriers between lab discoveries and clinical trials for new therapies, help interested parties utilize technical assistance available under the federal Food, Drug, and Cosmetic Act, and facilitate regular and ongoing communication and coordination with FDA to expedite the development and approval of high-need cures.

NIH will award contracts, grants, or cooperative agreements under CAN to eligible entities, which include biotechnology companies, pharmaceutical companies, private or public research institutions, institutions of higher education, medical centers, patient advocacy organizations, or academic research institutions. Grants will be awarded to promote innovations that support advanced research and development and production of high-need cures; accelerate the development of high-need cures; or help establish FDA-compliant protocols. Awards will not be more than \$15 million per project for the first FY for which the project is funded; additional funding in subsequent FYs can be applied for. Initial appropriations of \$500 million are authorized for FY 2010.

The CAN Review Board, which will advise and provide recommendations to the Director of NIH on the activities of CAN, will be comprised of 24 members serving four-year terms. Review Board members will represent the fields of basic research, medicine, biopharmaceuticals, discovery and delivery of medical products, bioinformatics and gene therapy, medical instrumentation, regulatory review and approval of medical products, and

disease advocacy organizations, as well as venture capital or private equity organizations. Ex-officio members will include representatives from NIH, the Department of Defense Office of Health Affairs, the Veterans Administration, the National Science Foundation, and FDA.

Centers of Excellence for Depression (Sec. 10410)

This section provides for the establishment of a group of national centers of excellence for depression through a series of five-year matching grants to institutions of higher education or public or private nonprofit research institutions with expertise in providing comprehensive health services focused on mental health services and depressive disorders. Funding in the amount of \$100 million is authorized for FYs 2011 through 2015, and \$150 million for FYs 2016 through 2020. If this requested funding is appropriated, 20 centers are to be established within one year of enactment of this legislation, and 30 by the end of FY 2016. A national coordinating center shall also be selected from among the grant recipients.

Programs Relating to Congenital Heart Disease (Sec. 10411)

This provision authorizes funding for a national congenital heart disease surveillance system, which seeks to enhance and expand the ability to track the epidemiology of congenital heart disease. It also strengthens NIH research in this regard.

Automated Defibrillation in Adam's Memory Act (Sec. 10412)

This section reauthorizes public access defibrillation programs through FY 2014.

Young Women's Breast Health Awareness and Support of Young Women Diagnosed With Breast Cancer (Sec. 10413)

This provision establishes a public education campaign focused on increasing breast health knowledge and awareness of breast cancer risks among women between the ages of 15 and 44, their physicians, and other health care professionals. It also directs CDC and NIH to conduct research relating to prevention of breast cancer in younger women, enhanced screening tests, and methods for prevention and early detection of breast cancer in young women. Finally, it provides funding for programs to assist young women diagnosed with breast cancer and pre-neoplastic breast disease. Nine million dollars for each FY between 2010 and 2014 is authorized for this program.

Title V—Health Care Workforce

Subtitle B—Innovations in the Health Care Workforce

National Health Care Workforce Commission (Sec. 5101)

The PPACA establishes the National Health Care Workforce Commission (Commission). Composed of 15 members selected by the Comptroller General, this Commission is charged with making recommendations "to develop a fiscally sustainable integrated workforce that supports a high-quality, readily accessible health delivery system that meets the needs of patients and populations...." The Commission's goal is to better address the nation's health care needs by actively examining health care workforce limitations, and developing courses of action to address those limitations, including a review of training and education capacity, and loan and grant programs. The Commission is charged with providing comprehensive and unbiased information to Congress and the administration on how to align federal health care workforce resources with current national needs, and to give priority to studying the nursing, oral health, mental and behavioral health, and allied and public health workforces.

State Health Care Workforce Development Grants (Sec. 5102)

At the state level, the PPACA establishes a competitive state health care workforce development grant program. This new grant program supports planning and implementation activities leading to comprehensive health care workforce development strategies at both state and local levels. These grants will support innovative approaches directed at improving the development, distribution, and delivery of the regional health care workforce.

Other Workforce Assessments:

Among other things, the PPACA codifies the existing national center and establishes several regional centers for health workforce analysis to collect and report data related to Title VII of the PHSA.³⁷ The regional centers also coordinate with state and local agencies in collecting labor and workforce statistical information to provide analyses and reports of Title VII to the Commission. (Sec. 5103)

³⁷ Programs under Title VII are designed to encourage health care workers to practice in underserved areas, increase the number of primary care providers, increase the number of minority and disadvantaged students enrolling in health care programs, and increase the number of faculty in health care education and training programs.

Subtitle C—Increasing the Supply of the Health Care Workforce

Loan Repayment / Grant Availability (Sec. 5201-5207, 10501 (l)(m))

The PPACA invests in and improves upon grants, scholarships, and loan repayment programs in the following fields: primary care, dentistry, pediatrics, nursing, and mental health. To make these financial improvements, the PPACA, among other things, eases current criteria for students to qualify for loans, shortens the period of time of certain required work commitments, and lessens the penalties for repayment non-compliance. Loan repayment is made available to certain pediatric, mental health, and behavioral health professionals, as well as to public health students and workers in exchange for working at least three years at a federal, state, local, or tribal public health agency. Loan repayment is also offered to allied health professionals employed at public health agencies or in settings providing health care in health professional shortage areas (HPSA), medically underserved areas, or areas of medically underserved populations. By helping to increase the workforce serving these areas, the PPACA seeks to address current health care workforce shortages.

The PPACA also provides grants for medical schools to establish recruiting programs for students from medically underserved areas who would like to return to serve their hometown after finishing medical school. These programs would provide students with specialized training in rural health issues and ultimately help students find residencies that train doctors to serve rural or underserved communities. The PPACA also amends and reauthorizes section 768 of the PHSA, the preventive medicine and public health residency program.

Funding for the National Health Service Corps (Sec. 5207, 10501(n)(1), 10503)

By way of background, the National Health Service Corps (NHSC), through scholarship and loan repayment programs, helps HPSAs receive adequate medical, dental, and mental health service providers. The NHSC scholarship program pays tuition and fees to students enrolled in accredited medical, dental, nurse practitioner, certified nurse midwife, and physician assistant training. In addition, the NHSC loan repayment program offers fully trained primary care physicians, family nurse practitioners, physician assistants, dentists, and other health care workers \$50,000 to repay student loans in exchange for two years serving in a community-based site in a high-need HPSA approved by the NHSC.

The PPACA increases and extends the authorization of appropriations for the NHSC scholarship and loan repayment program. The loan repayment amount allows for half-time service and teaching to count for up to 20% of the Corps service commitment. It provides \$1.5 billion in mandatory funding to support primary care providers who commit to practice in underserved communities. To provide this funding, the PPACA establishes a Community Health Centers and NHSC Fund. These funds create an increased and expanded national investment in community health centers under section 330 of the PHS and the NHSC.

Other Programs to Increase the Current Health Care Workforce Supply

Among other things, the PPACA:

- Increases loan amounts and extends the student enrollment dates for certain nursing schools loans funding under the PHS. (Sec. 5202)
- Provides grants for state and local programs to award scholarships to mid-career public and allied health professionals working in public and allied health positions at the federal, state, tribal, or local level so that they might receive additional training in public or allied health fields. (Sec. 5206)
- Creates a \$50 million grant program administered by the Health Resources Services Administration to support nurse-managed health clinics. (Sec. 5208)
- Eliminates the artificial cap on the number of Commissioned Corps members, allowing the NHSC to expand to meet national public health needs. (Sec. 5209)
- Establishes a Ready Reserve Corps within the Commissioned Corps for service in times of national emergency. Ready Reserve Corps members can be called to active duty to respond to national emergencies and public health crises. (Sec. 5210)

Subtitle D—Enhancing Health Care Workforce Education and Training

Financial Support for Health Care Workforce Training (Sec. 5301-5315)

Section 5301 of the PPACA has several provisions aimed at enhancing both education and training in family medicine, general internal medicine, general pediatrics and physician assistantship. More specifically, the PPACA provides grants to develop and operate training programs, provides financial assistance to trainees and faculty, and enhances faculty development in primary care and physician assistant programs. Those programs that educate students in team-based approaches to care, including those that focus on patient-centered medical homes among other things, will receive priority. In addition, increased funding is provided over the next three years to establish new training opportunities for direct care workers providing long-term care and support. Section 5303 also provides funding for general, pediatric, and public health dentistry in Title VII of the PHS. This will allow dental schools and education programs to use current grants for pre-doctoral training, faculty training, faculty development and dental faculty loan repayment.

Nursing Loan Repayment

The PPACA awards grants to nursing schools with the goal of strengthening nurse education and training programs to help improve nurse retention. A federally funded student loan repayment program for nurses with outstanding debt is available for those nurses who pursue a career in nurse education. To be eligible for loan repayment, a nurse must agree to teach at an accredited school of nursing for at least four years within a six-year period. To support this loan repayment plan, the PPACA authorizes \$338 million to fund Title VIII of the PHS.

nursing programs.³⁸ The PPACA also strengthens language for accredited nurse midwifery programs to receive advanced education grants.

Other Financial Support for Training Programs

Among other things, the PPACA:

- Authorizes funding over three years to establish new training opportunities for direct care workers providing services and support in long-term care settings, intermediate care facilities for individuals with mental retardation, and home and community-based programs. (Sec. 5302)
- Authorizes the Secretary to award grants to establish training programs for alternative dental health care providers to increase access to dental care in rural, tribal and medically underserved areas. (Sec. 5304)
- Reauthorizes and expands geriatric education programs to help focus on caring for the country's aging population. It also authorizes funding to geriatric education centers to support chronic care management and long-term care for faculty in health-professions schools. (Sec. 5305)
- Awards grants to schools for the development, expansion, or enhancement of training programs in social work, professional training in child and adolescent mental health and pre-service or in-service training to paraprofessionals in child and adolescent mental health. (Sec. 5306)
- Reauthorizes and expands programs that support the development and evaluation of model curricula for cultural competency, prevention and public health proficiency, and aptitude for working with individuals with disabilities. (Sec. 5307)
- Authorizes CDC in collaboration with the Secretary to award grants to promote positive health behaviors and outcomes through use of community health workers (individuals who promote health or nutrition) in medically underserved communities. (Sec. 5313)
- Expands CDC fellowship training programs in applied health epidemiology, public health laboratory science, public health informatics, and expansion of the Epidemic Intelligence Service. (Sec. 5314)
- Authorizes the Surgeon General to establish a U.S. Public Health Sciences Track to train physicians, dentists, nurses, physician assistants or nurse practitioners, mental and behavioral health specialists, pharmacists, and other public health professionals. This track will emphasize patient-centered, interdisciplinary, and care coordination skills, as well as emergency preparedness and response. (Sec. 5315)
- Establishes faculty at schools for physician assistants as eligible for faculty loan repayment within the workforce diversity program. (Sec. 10501)

³⁸ Title VIII programs focus on training advanced practice nurses, increasing the number of minority and disadvantaged students enrolling in nursing programs, and improving nurse retention through career development and improved patient care systems.

Subtitle E—Supporting the Existing Health Care Workforce

Centers of Excellence Program (Sec. 5401)

The Centers of Excellence program, charged with developing a minority applicant pool to enhance recruitment, training, academic performance, and other support for minorities interested in careers in health, is reauthorized.

Increasing Workforce Diversity (Sec. 5402, 5404)

The PPACA provides support for pipeline programs for health professions that assist in the recruitment and retention of underrepresented minorities and individuals from disadvantaged backgrounds. It also provides loan repayment programs for faculty from those same backgrounds, and financial support for institutions that train nurses to increase diversity among these professionals. Nursing diversity grants can now be used to include completion of associate degrees, bridge or degree completion programs, or advanced degrees in nursing, as well as pre-entry preparation, advanced education preparation and retention activities. The PPACA also provides scholarships for disadvantaged students who commit to work in medically underserved areas as primary care providers, and expands loan repayments for individuals who will serve as faculty in eligible institutions. Scholarship funding is increased from \$37 million to \$51 million for FY 2011 through 2014.

Interdisciplinary Community-Based Training (Sec. 5403)

The PPACA authorizes funding to establish community-based training and education for area health education centers and programs. Two types of awards are provided, Points of Service Maintenance and Enhancement Awards and Infrastructure Development Awards. Both of these programs target individuals who are seeking careers in the health professions and are from disadvantaged and rural underserved communities.

Primary Care Extension Program (Sec. 5405)

The PPACA creates a primary care extension program to provide support and assistance to primary care providers, so that they in turn can provide education and assistance to providers about evidence-based therapies, preventive medicine, health promotion, chronic disease management, and mental and behavioral health services. In addition, the Agency for Healthcare Research and Quality will award planning and program grants to establish state hubs, including the state health department, and state-level entities administering Medicaid and Medicare.

Subtitle F—Strengthening Primary Care and Other Workforce Improvements

Expanding Access to Primary Care Services and General Surgery (Sec. 5501)

To strengthen the primary care workforce, the PPACA provides a variety of incentives. Beginning in 2011, primary care practitioners (defined as physicians with a primary specialty designation of family, internal, geriatric, or pediatric medicine, or a nurse practitioner, clinical nurse specialist, or physician assistant, for whom primary care services accounted for at least 60% of allowed charges during designated periods) are provided with a 10% Medicare payment bonus for five years for services relating to specified codes. General surgeons practicing in HPSAs are also provided with 10% payment bonuses for certain major surgical procedures.

Medicare Federally Qualified Health Center (FQHC) Improvements (Sec. 5502)

The Secretary is also directed to develop and implement a prospective payment system for Medicare-covered services furnished by FQHCs. FQHCs are "safety net" providers, such as community health centers, public housing primary care centers, outpatient health programs funded by the Indian Health Service, and programs serving migrants and the homeless. The purpose of the FQHC program is to enhance the provision of primary care services in underserved urban and rural communities. The PPACA also adds Medicare-covered preventive services to the list of services eligible for reimbursement when furnished by an FQHC.

Residency Programs (Sec. 5503-5506)

The PPACA updates and modifies existing Social Security Act provisions on distributing additional residency positions. Beginning in 2011, certain hospitals with unused resident positions will have their resident limits reduced. Other hospitals may apply for increase in their resident limits, to be filled by primary care or general surgery residents. Special preference will be given to programs located in states with low physician-resident-to-general-population ratio, to programs located in states with the highest ratio of population living in HPSAs relative to the general population, and to programs in rural areas. The Secretary is also charged with redistributing medical residency slots from closed hospitals.

The PPACA allows for the counting of resident time in outpatient nonprovider settings by modifying the rules governing when hospitals can receive indirect medical education (IME) and direct graduate medical education (DGME) funding for residents who train in a nonprovider setting. With this modification any time spent by the resident in a nonprovider setting will be counted toward DGME and IME if the hospital covers the costs of the stipends and any fringe benefits. The PPACA also modifies the rules for counting resident time to include didactic conferences and other scholarly activities.

Programs Aimed at Low-Income Populations (Sec. 5507)

The PPACA establishes a demonstration project to provide through states, Indian tribes, academic centers, and other eligible entities, aid and supportive services to low-income individuals, to enable them to obtain education and training for well-paid occupations in the health care field that are expected to experience labor shortages or be in high demand. The PPACA also establishes a demonstration program to develop training and certification programs for personal and home care aides.

Support for Primary Care Residency Programs (Sec. 5508)

The PPACA amends the PHSA to provide for grants for "teaching health centers" establishing new accredited or expanded primary care residency programs. A teaching health center is a community based, ambulatory patient care center, and specifically includes FQHCs and certain other outpatient clinics. The total appropriations for these grants are \$25 million for 2010 and \$50 million for both 2011 and 2012. The PPACA allocates payments to teaching health centers for direct and indirect costs related to training primary care residents in certain expanded or new programs. The PPACA appropriates a total of \$230 million in funding for such payments for FYs 2011 through 2015.

Graduate Nurse Education Programs (Sec. 5509)

The PPACA authorizes the Secretary to establish a demonstration program to increase funding for up to five hospitals for graduate nurse education training to advance practice nurses (including nurse specialists, practitioners, anesthetists, and midwives). To support this program, \$50 million is to be appropriated from the Medicare Hospital Insurance Trust fund for each of FYs 2012 – 2015. By 2017, the Secretary must deliver a report to Congress on the progress of the demonstration program, including the growth in the number of advanced practice registered nurses and the costs to the Medicare program as a result of this program.

Subtitle G—Improving Access to Health Care Services

Improving Access to Health Care Services (Sec. 5601-5605 and 10504)

Improving access to health care services is another key area addressed by the PPACA. The PPACA increases the spending for FQHCs from \$2.98 billion in 2010 to \$8.33 billion in 2015. It also directs the Secretary, in consultation with stakeholders, to engage in negotiated rulemaking to establish a comprehensive methodology and criteria for designating medically underserved populations and HPSAs.

Increasing Access through Financial Incentives

Among other things, the PPACA:

- Reauthorizes the Wakefield Emergency Medical Services for Children program to award grants to states and medical schools to support the improvement and expansion of emergency medical services for children needing trauma or critical care treatment. (Sec. 5603)
- Provides \$50 million in grants for coordinated and integrated services through the co-location of primary and specialty care in community-based mental and behavioral health settings. (Sec. 5604)
- Establishes a Commission on Key National Indicators to conduct a comprehensive oversight of a newly established key national indicators system, in coordination with the National Academy of Sciences. (Sec. 5605)
- Provides funding to HHS for construction or debt service on hospital construction costs for a new health facility meeting certain criteria. (Sec. 10502)
- Directs the Secretary to establish a three-year demonstration project in 10 states to provide comprehensive health care services to the uninsured at reduced fees. (Sec. 10504)

Title VI—Transparency and Program Integrity

Subtitle A—Physician Ownership and Other Transparency

Limitation on Referrals by Physicians to Hospitals in Which They Own Interests (Sec. 6001, Reconciliation Act Sec. 1106)

Section 6001 of the PPACA, as amended by section 1106 of the Reconciliation Act, severely limits the growth of the burgeoning physician-owned hospital industry. Currently, the Stark Law's "whole hospital exception" permits physicians to refer to hospitals in which they own interests if the ownership is in the entire facility and not merely a department or division of the hospital. Among other things, the PPACA, as amended by the Reconciliation Act, provides that the "whole hospital exception" will now only apply to protect physician ownership either in hospitals that already possess Medicare provider numbers or that obtain them by the end of the year. In summary, the PPACA provides that, without relying on some other Stark Law exception, new physician-owned hospitals may not be created in the future, and even existing physician-owned hospitals will not be able to expand. The PPACA, as modified by the Reconciliation Act, specifically dictates the following for physician-owned hospitals:

- **"Grandfathered" Facilities.** All existing physician-owned hospitals that possess a Medicare provider agreement as of December 31, 2010 will be "grandfathered" in that they will be able to continue to rely on the protection afforded by the "whole hospital exception."³⁹ No other mechanism is included to permit projects that are "under development" to petition to be exempted. Such a provision was included in the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which imposed a moratorium on the opening of new specialty hospitals while Congress studied such providers.
- **Extent of Physician Ownership.** The PPACA provides that the percentage of physician ownership law is in place as of the "date of the enactment" of the PPACA cannot increase. There is, however, no requirement that the identity of particular physicians remain the same. As a result, physician-owned shares can change hands as long as the total percentage of physician ownership does not increase.
- **Limitation on Expansion.** Except as permitted in only very limited circumstances, the PPACA severely restricts any possible expansion in the number of operating rooms, procedure rooms and beds beyond those existing as of the date of enactment of the PPACA. Studies have shown that virtually no existing physician-owned hospitals will

³⁹ Section 6001(a)(2)(C) of the PPACA suggests that a hospital may be grandfathered if it has physician ownership and a provider agreement not later than 18 months after the date of enactment of the PPACA. However, when this language is read in connection with section 6001(a)(3), as amended by the Reconciliation Act, it is clear that the "grandfathering" date is December 31, 2010.

- be able to satisfy the requirements for expansion contained in the PPACA. The PPACA, as amended by the Reconciliation Act, also permits hospitals that treat a considerable number of Medicaid patients to expand.⁴⁰ It is unclear how many existing hospitals will be able to take advantage of that provision.
- **Provisions Related to Conflicts of Interest.** The PPACA includes a number of provisions directed at limiting perceived conflicts of interests. These provisions consist of the requirement that hospitals notify HHS annually of the identity of each physician owner, and the nature and extent of such owner's interest in the hospital. Further, each physician-owned hospital is required to include a mechanism to insure that referring physician-owners disclose to their patients their ownership in the hospital prior to a patient's admission to it. The hospital may not condition any physician-ownership interests on the physician making or influencing referrals to the hospital. Finally, physician-owned hospitals are required to disclose the fact that their owners include physicians in any public website or public advertising.
 - **Provisions Relating to the Nature of Ownership, Ownership in Hospitals.** Congress' focus on physician ownership in hospitals has often been directed at the terms upon which the physicians obtained their ownership. Consequently, the PPACA contains provisions that require that (1) interests be offered to physicians on terms not more favorable than those on which a non-physician could acquire them; (2) neither the hospital nor any of its investors may finance the purchase of interests in the hospital for a physician-owner, or guarantee such financing; and (3) distributions be made solely on the basis of each physician's proportion of ownership in the hospital without taking into account the volume of referrals.
 - **Ownership in Ancillary Items.** With the advent of restrictions on physician ownership in hospitals being long foreseen, participants in the industry have been considering other means through which physicians might participate in the ownership of at least some ancillary aspects of a hospital project, such as real estate. The PPACA indicates that ownership in even ancillary aspects is also under scrutiny. For example, the PPACA mandates that physician owners cannot receive "or be guaranteed the right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors...." Further, any purchase of interests must not be undertaken on terms more favorable than those that were available to non-physicians. Although it is unclear what is targeted by these provisions, they seem, on their face, to clash with well-established and frequently used Stark Law

⁴⁰ Section 1106 of the Reconciliation Act defines a 'high Medicaid facility' as a hospital that (1) is not the sole hospital in a county; (2) with respect to each of the three most recent years for which data is available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and (3) does not discriminate (and does not permit physicians practicing at such hospital to discriminate) against beneficiaries of federal health care programs.

and anti-kickback safe harbors, which protect investments in real estate and equipment on fair market value terms by referral sources such as physicians. This appears to be another area in which clarifying regulations are required.

- **Patient Safety.** Considerable attention has previously been focused by Congress on whether physician-owned hospitals truly act as hospitals and not merely as large ASCs. An example of this focus has been the emphasis placed on the manner in which these facilities respond to emergencies. The PPACA addresses this by requiring that all physician-owned hospitals provide for proper assessment of patients, with the ability to refer and transfer those patients requiring greater resources to more acute hospitals. The hospital must also disclose to, and obtain a signed acknowledgement from, a patient if the hospital does not have a physician available on the premises during all hours in which the hospital is providing services to that patient.
- **Provisions Applicable to ASCs Converted into Hospitals.** Recognizing that many physician-owned hospitals were once ASCs, the PPACA specifically provides that a hospital cannot be grandfathered if it was converted from an ASC to a hospital on or after the date of the enactment of the PPACA. This apparently does not suggest that a hospital, which obtained a provider number prior to the date the PPACA was enacted, could not have been an ASC at one time.

Transparency Reports and Reporting of Physician Ownership or Investment Interests (Sec. 6002)

The PPACA incorporates many of the provisions of the Physician Payment Sunshine Act that Sen. Charles Grassley (R-Iowa) introduced several years ago to encourage greater transparency in the relationships between drug and device companies and physicians.

Beginning March 31, 2013, and annually thereafter, any manufacturer of a covered drug, device, biological or medical supply⁴¹ that provides a payment or other transfer of value to a "covered recipient" – a physician or a teaching hospital – must submit to the Secretary, in electronic form, the following information:

- The covered recipient's name and business address
- If a physician, the physician's specialty and national provider identifier
- The amount of the payment or other transfer of value and the dates on which it was provided to the covered recipient
- A description of the form of the payment or other transfer of value (e.g., cash or cash equivalent, in-kind items or services, stock or stock options)
- A description of the nature of the payment or other transfer of value (e.g., consulting fees, honoraria, gift, entertainment, food, travel, education, research, charitable contribution)

⁴¹ A "covered drug, device, biological, or medical supply" is any product for which payment is available under a federal health care program, such as Medicare or Medicaid.

- If the payment or other transfer of value is related to the marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of such drug, device, biological, or medical supply
- Any other categories of information that the Secretary determines to be appropriate

If a manufacturer provides a payment or other transfer of value to an entity or individual *at the request of or designated on behalf of* a covered recipient, the manufacturer must disclose that payment or other transfer of value under the name of the covered recipient.

In addition, the PPACA requires manufacturers and group purchasing organizations (GPOs) that purchase, arrange for, or negotiate the purchase of covered products to submit to the Secretary certain information regarding ownership or investment interests held by a physician (or an immediate family member of the physician) in the manufacturer or GPO during the preceding year. This reporting requirement does not include a physician's ownership or investment interest in a publicly traded security and mutual fund.

Beginning September 30, 2013, and on June 30 of each year thereafter, the Secretary will make all payment, ownership interest, and enforcement information publicly available on the Internet via a searchable website.

That said, the PPACA provides for delayed publication of payments made under product research or development agreements, and for clinical investigations. Specifically, for payments or other transfers of value made to covered recipients under product research or development agreements for services furnished in connection with research on a potential new medical technology, or a new application of an existing technology, or the development of a new drug, device, biological, or medical supply, or in connection with a clinical investigation of a new drug, device, biological, or medical supply—the information will not be made available to the public until the earlier of the following: the date of FDA approval or clearance of the product; or four calendar years after the date such payment or other transfer of value is made.

The definition of "payment or other transfer of value" does not include the following, and as such, these items do not need to be reported to the Secretary:

- Payments or transfers of value of less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the manufacturer during the calendar year exceeds \$100 (adjusted annually for inflation)
- Product samples that are not intended to be sold and are intended for patient use
- Educational materials that directly benefit patients or are intended for patient use
- Loan of a covered device for a short-term trial period, not to exceed 90 days
- Items or services provided under a contractual warranty, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in his or her professional capacity

- Discounts and rebates
- In-kind items used for the provision of charity care
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund
- In the case of a manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan
- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional
- Compensation paid by a manufacturer to a covered recipient who is directly employed by and works solely for that manufacturer or distributor

The penalties for failure to report include civil monetary penalties of not less than \$1,000, but not more than \$10,000, for each payment or other transfer of value or ownership or investment interest that is not reported (not to exceed \$150,000). A "knowing" failure to report will result in even higher penalties. Funds collected by the Secretary as a result of the imposition of a civil monetary penalty will be used to carry out this law.

Not later than October 11, 2011, the Secretary shall establish procedures for manufacturers and GPOs to submit information to the Secretary and for the Secretary to make such information available to the public. In addition, effective January 1, 2012, this law will preempt any state laws that require a manufacturer to disclose or report the type of information described above regarding payments or other transfers of value made to covered recipients. However, the law will *not* preempt any state laws that require the disclosure or reporting of information that falls outside of the scope of the above requirements.

Currently, 5 states – Maine, Massachusetts, Minnesota, Vermont and West Virginia, as well as the District of Columbia – have enacted unique laws regarding the financial arrangements between drug and/or device companies and health care professionals. Other states, such as California and Nevada, require companies to adopt a marketing code of conduct, which is not addressed at all in the PPACA. This means that companies will have to continue to report certain expenditures and make compliance certifications to state authorities.

Most significantly, the new law applies only to payments or other transfers of value to physicians and teaching hospitals, whereas many of the state laws cover payments made to a broad range of individuals and entities, including hospitals, nursing homes, pharmacists, and all individuals authorized to prescribe, dispense, or purchase prescription drugs or medical devices. In addition, while under the federal law many items are exempt from the reporting requirements, such as loans of medical devices and charitable contributions, some states, such as Vermont, require that these types of interactions with covered recipients be disclosed.

Disclosure of Certain Self-Referred Imaging Services (Sec. 6003)

For physicians who order tests for their own patients in reliance on the Stark in-office ancillary services exception for MR, CT and PET services (and for other designated health services as determined by the Secretary), such physicians are required to inform their patients in writing that the services can be obtained elsewhere, and they must provide the patient with a list of suppliers of the imaging services in the area where the individual resides.

Prescription Drug Sample Transparency (Sec. 6004)

Beginning April 1, 2012, and annually thereafter, each manufacturer and authorized distributor of record of a prescription drug for which payment is available under Medicare or Medicaid must submit to the Secretary, for the preceding year, the identity and quantity of drug samples requested under the federal Food, Drug, and Cosmetic Act, and the identity and quantity of drug samples distributed under such Act, aggregated by the name, address, professional designation, and signature of the practitioner making the request, or of any individual who makes or signs for the request on behalf of the practitioner.

Pharmacy Benefit Managers' Transparency Requirements (Sec. 6005)

A health benefits plan or pharmacy benefits manager (PBM) that manages prescription drug coverage under contract with a PDP sponsor of a prescription drug plan, or an MA organization offering an MA-PD plan under Medicare Part D, or a qualified health benefits plan offered through an exchange established by a state under the PPACA, must provide the following information to the Secretary and, in the case of a PBM, to the plan with which it contracts:

- The percentage of all prescriptions that were provided through retail pharmacies compared with mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed, by pharmacy type, that is paid by the health benefits plan or PBM under the contract.
- The aggregate amount, and the type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan, along with the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.
- The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies and mail order pharmacies, and the total number of prescriptions that were dispensed.

The information disclosed above will remain confidential and can only be disclosed by the Secretary – in a form that does not disclose the identity of a specific PBM, plan, or prices charged for drugs – for certain specific purposes, such as to permit the Comptroller General or the Director of the CBO to review the information provided.

The PPACA allows the Secretary to specify how and when the implementation of these transparency requirements will occur. Also, penalties will apply for failure to timely provide the above information or for knowingly providing false information.

Subtitle B—Nursing Home Transparency and Improvement

Part I—Improving Transparency of Information

The PPACA incorporates many of the provisions contained in earlier legislation introduced by Sens. Kohl (D-Wis.) and Grassley, and Congressman Stark (D-Cal.) and Congresswoman Schakowsky (D-Ill.), known as the Nursing Home Transparency and Improvement Acts. This legislation is intended to expand public disclosure about the ownership and operations of Medicare SNFs and Medicaid nursing facilities in an effort to make facilities and their owners/operators more accountable, increase penalties for noncompliance, improve staff training, and increase the quality of nursing home care.

Required Disclosure of Ownership and Additional Disclosable Parties Information (Sec. 6101)

Under existing law (Section 1124 of the Social Security Act), Medicare providers, including SNFs, are required to disclose (1) any person or entity that owns directly or indirectly an ownership interest of 5% or more, (2) officers and directors (if a corporation) and partners (if a partnership), and (3) holders of a mortgage, deed of trust, note or other obligation secured by the entity or the property of the entity. This information is typically disclosed on the CMS Form 855A and, in some states, on the CMS Ownership and Control Interest Statement.

The PPACA expands the information required to be disclosed to include the facility's organizational structure, as well as additional information on officers, directors, trustees and managing employees of the facility, including names, titles and start dates of service. The term "managing employee" is broadly defined as an individual (including a general manager, business manager, administrator, director, or consultant) who directly or indirectly manages, advises or supervises any element of the practices, finances, or operations of the facility.⁴²

The legislation also requires information on any additional disclosable party of the facility. "Additional disclosable party" means, for any facility, any person or entity that (1) exercises operational, financial, or managerial control over the facility, or provides policies or procedures for the operations of the facility, or provides financial or cash management services to the facility; (2) leases or subleases real property to the facility, or owns a whole or part interest equal to or exceeding 5% of the total value of such real property; or (3) provides management or

⁴² Note that the definition of "managing employee" for nursing home disclosure purposes is different from the definition of "managing employee" for purposes of other ownership and disclosure provisions of the law. See section 1126(b) of the Social Security Act.

administrative services, management or clinical consulting services, or accounting or financial services to the facility. Notably, the bill deleted earlier definitions that would have required disclosures of parties lending funds to the facility and other providers, such as therapy companies and hospice organizations providing services to the facility.

Effective upon enactment, facilities must have the information available for submission to the Secretary of HHS, the OIG, the state in which the facility is located and the state long-term care ombudsman upon request. Within two years from the date of enactment, the Secretary is required to issue regulations requiring the information to be reported to the Secretary in a standard format. Facilities will be required to certify that the information is, to the best of the facility's knowledge, "accurate and current." Within one year after final regulations are issued, facilities will be required to make the information available to the public in accordance with procedures established by the Secretary. In the interim, we would expect CMS to issue subregulatory guidance to facilities on how to compile the information to be available to the government agencies upon request.

Accountability Requirements for SNFs and Nursing Facilities (Sec. 6102)

Currently, compliance programs are generally voluntary or required as part of settlements of cases with the government, e.g., corporate integrity agreements. In the PPACA, for the first time SNFs and nursing facilities will be required to have a compliance and ethics program operational within 36 months of enactment. The program must be effective in preventing and detecting criminal, civil and administrative violations and in promoting quality care. The Secretary is required to issue regulations to implement this section, which may include a model compliance program. There are eight required components of a compliance and ethics program, similar to the eight elements of a compliance program as issued by the OIG in its voluntary compliance program guidance documents. Within three years from issuing final regulations, the Secretary will be required to evaluate the compliance and ethics programs established by facilities, and submit a report to Congress on the study's findings, including recommendations regarding changes in the requirements for such programs.

The PPACA also requires the Secretary to establish and implement a quality assurance and performance improvement program for facilities by December 31, 2011. Under this program, the Secretary must establish standards relating to quality assurance and performance improvement, and provide technical assistance to facilities on the development of best practices to meet such standards. Within a year of the Secretary's promulgation of regulations to carry out this program, a facility must submit its plan to meet these standards and best practices.

Other Nursing Home Provisions (Sec. 6103 – 6107)

Among other things, the PPACA:

- Requires the Secretary to include certain information on the Nursing Home Compare Medicare website, such as: staffing data for each facility; links to state Internet websites

- with information regarding state survey and certification programs and inspection reports; summary information on the number, type, severity, and outcome of substantiated complaints; and the number of adjudicated instances of criminal violations by a facility. (Sec. 6103)
- For cost reporting periods beginning two years from enactment of the law, requires facilities to separately report expenditures for wages and benefits for direct care staff. (Sec. 6104)
 - Requires the Secretary to develop a standardized complaint form for use by a resident (or someone acting on the resident's behalf) in filing a complaint with a state survey and certification agency, and a state long-term care ombudsman program. (Sec. 6105)
 - Requires that within two years of enactment of the law, facilities must electronically submit to the Secretary direct care staffing information based on payroll and other verifiable and auditable data in a uniform format. (Sec. 6106)
 - Directs the Comptroller General to conduct a study of the CMS 5-Star Quality Rating System for nursing homes, to evaluate how the system is being implemented, whether any problems are associated with the system or its implementation, and how the system could be improved. Within two years, the Comptroller General must submit a report to Congress on the study's findings. (Sec. 6107)

Part II—Targeting Enforcement

Civil Money Penalties (Sec. 6111)

Under existing law, the Secretary may impose a civil monetary penalty (CMP) in an amount not to exceed \$10,000 for each day of noncompliance. The new legislation adds a section stating that where a facility self-reports and promptly corrects a deficiency within 10 calendar days, the Secretary may reduce the amount of the penalty by up to 50%. However, reductions will not be made for more than one self-reported deficiency per year, or for self-reported deficiencies that are found to result in a pattern of harm or widespread harm, that immediately jeopardize the health or safety of a resident, or that result in the death of a resident.

In addition, the Secretary is directed to issue regulations that would allow a facility to have an independent informal dispute resolution process that generates a written record within 30 days of imposition of a CMP, and prior to collection of the CMP. The Secretary also may provide for the collection and placement of the CMP amount in an escrow account, pending the resolution of any dispute resolution and appeal. If an appeal is successful, the facility would receive a refund of the collected amounts (with interest). If an appeal is unsuccessful, the Secretary may provide that some portion of the amount held in escrow be used to support activities that would benefit residents.

National Independent Monitor Demonstration Project (Sec. 6112)

The PPACA directs the Secretary, along with the OIG, to conduct a demonstration project to develop, test, and implement an independent monitor program to oversee interstate and large

intrastate chains of SNFs and nursing facilities. The demonstration project must be implemented within a year of the law's enactment, and will last for two years.

Chains will be responsible for a portion of the costs associated with the appointment of independent monitors under the demonstration project. After the demonstration project is over, the Secretary and the OIG will evaluate the project and, within 180 days of its completion, the Secretary must submit a report to Congress with its findings, together with recommendations as to whether the project should be established on a permanent basis.

Notification of Facility Closure (Sec. 6113)

Effective one year after enactment, a facility administrator must provide written notification of an impending closure of a facility to the Secretary, the state long-term care ombudsman, residents, and legal representatives within 60 days of such closure. If applicable, the notice must include a plan for the transfer and relocation of residents before the facility closes. An administrator also must ensure that the facility does not admit new residents after such notice is provided. Failure to comply with this section could result in CMPs of up to \$100,000 and exclusion from participation in any federal health care program.

National Demonstration Projects on Culture Change and Use of Information Technology in Nursing Homes (Sec. 6114)

The PPACA directs the Secretary to conduct two demonstration projects, one for the development of best practices in SNFs and NFs that are involved in the culture change movement, and one for the development of best practices in SNFs and nursing facilities for the use of information technology to improve resident care. For each project, the Secretary will award one or more grants to facility-based settings. The demonstration projects can last up to three years and must be implemented within a year. Within nine months of completion of a demonstration project, the Secretary must submit a report to Congress on its findings and recommendations.

Part III—Improving Staff Training

Dementia and Abuse Prevention Training (Sec. 6121)

The PPACA requires facilities to include dementia management and patient abuse prevention training as part of initial nurse aide training and competency evaluation programs, effective a year from enactment. This section also amends the definition of nurse aide to include an individual who provides services through an agency or under contract with the facility.

Subtitle C—Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long-Term Care Facilities and Providers

Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long-Term Care Facilities and Providers (Sec. 6201)

The PPACA directs the Secretary to establish a nationwide program to identify efficient, effective, and economical procedures for long-term care facilities or providers to conduct background checks on prospective direct patient access employees. The Secretary must conduct the nationwide program under similar terms and conditions as the pilot program of the same name described in section 307 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with a few modifications. For example, the Secretary must enter into agreements with each state that applies and agrees to conduct background checks under the nationwide program on a statewide basis. States will be responsible for monitoring compliance with the requirements of the nationwide program and will be required to have specified compliance procedures in place. States will receive matching funds to conduct these activities.

Long-term care facilities or providers will be required to obtain state and national criminal history background checks on their prospective employees through such means as the Secretary determines appropriate. To conduct these checks, providers will use a search of state-based abuse and neglect registries and other specified state and federal databases and records, including a fingerprint check.

The OIG is required to conduct an evaluation of the nationwide program and to submit a report to Congress within 180 days of the program's completion.

Subtitle D—Patient-Centered Outcomes Research

Comparative Clinical Effectiveness Research (Sec 6301)

Section 6301 establishes a private, nonprofit corporation to be called the Patient-Centered Outcomes Research Institute (PCORI or Institute) governed by a public-private Board of Governors appointed by the Comptroller General, to include the Director of NIH and the Director of the Agency for Healthcare Quality and Research. The Institute will identify national priorities for comparative effectiveness research, taking into account, among other factors, disease incidence, burden, gaps in clinical evidence, and "the effect on national expenditures" of a health care treatment strategy. The Institute's work will be transparent, with the public afforded an opportunity to comment on the research agenda, as well as on published reports of research. In addition, CMS may use the research findings of the Institute in making coverage decisions only through a transparent process that includes public comment. The Institute will carry out the comparative effectiveness research agenda through contracts with existing federal agencies, academic research centers, and the private sector.

The research to be pursued is completely open-ended and will include studies to measure the comparative clinical effectiveness, risks and benefits of: health care interventions, treatment protocols, medical devices, drugs, biologics, and any other treatments or strategies being used in prevention, diagnosis or management of illness and injury. One specific enhancement to the authority of the Institute is access to the claims data collected by CMS. Researchers have long maintained that the Medicare Parts A, B, C and D claims databases contain highly valuable information – for example on disease occurrence and effectiveness measured by inpatient readmission – that has never been mined and developed. In addition, the Institute will have authority to allow research organizations to pay copayments and coinsurance for study subjects to facilitate a blinded study, or otherwise preserve the integrity of the protocol.

The activities of PCORI will be paid for by a tax on insurance policies of \$2.00 per covered life beginning in 2012. The CBO estimates that the tax would raise \$2.6 billion through 2019.

Finally, upon the enactment of the Act, section 6302 terminates the prior authority to create the "Federal Coordinating Council for Comparative Effectiveness Research" contained in ARRA.

Subtitle E—Medicare, Medicaid, and CHIP Program Integrity Provisions

Provider Screening and Other Enrollment Requirements under Medicare, Medicaid, and CHIP (Sec. 6401)

Provider Screening. This provision requires the Secretary, in consultation with the OIG, to establish procedures for screening providers and suppliers participating in federal health care programs (specifically, Medicare, Medicaid, and CHIP). The Secretary has authority to set different levels of screening depending upon the type of provider or supplier. At a minimum, all providers and suppliers would be subject to licensure checks, and additional screening items could include fingerprinting, criminal background checks, multi-state database inquiries, and surveys/site visits. An application fee of \$200 for individual practitioners and \$500 for institutional providers and suppliers would be imposed to cover the costs of screening each time they re-verify their enrollment (every five years). Section 10603 removes the enrollment fee for physicians. This section also provides for a provisional enrollment for new providers and suppliers, during which CMS could improve pre-payment review and payment caps.

This provision is intended to address rising enrollment fraud, especially among suppliers. The new paradigm for supplier fraud is for a false entity to enroll and submit as many false claims as possible, often using stolen beneficiary data. Claims are required to be promptly paid under separate regulation. These entities then close up and move on – literally "taking the money and running." Not surprisingly, these provisions (like others in this Part) are likely to cause a significant administrative burden among law-abiding providers and suppliers. Because the law provides for interim final rulemaking on this point, CMS may move quickly to implement these provisions.

Disclosure of Deadbeat or Excluded Affiliates. New enrollees in Medicare, Medicaid or CHIP will be subject to disclose current or previous affiliations with any provider or supplier that has

uncollected debt, has had their payments suspended, has been excluded from participating in a federal health care program, or has had their billing privileges revoked.

Mandatory Compliance Programs. The Secretary, in consultation with OIG, will require certain providers and suppliers to have mandatory compliance programs. Implementation and other details will be determined by later regulation.

The details on this provision are to be determined by regulation. But it is no secret that the OIG has long wished to impose mandatory compliance programs on providers and suppliers. Usually the imposition of such programs is in the form of a Corporate Integrity Agreement (CIA) – a contract where the consideration by the OIG is the release of its permissive exclusion authority. In return, the provider or supplier agrees to implement certain structural, training, and reporting obligations, and if these obligations are not met, the entity can be excluded from federal health care programs. While it is likely that these mandatory programs will have some of the same elements as a CIA, it will be interesting to see what the remedy is for non-compliance, since this provision does not authorize exclusion or any other penalties.

Enhanced Medicare and Medicaid Program Integrity Provisions (Sec. 6402)

Integrated Data Repository. This provision is intended to allow federal regulators the ability to correlate claims and payment data across programs and within programs to identify fraud. CMS must include in the integrated data repository (IDR) claims and payment data from the following programs: Medicare (Parts A, B, C, and D), Medicaid, CHIP, health-related programs administered by the Departments of Veterans Affairs (VA) and Defense (DOD), the Social Security Administration, and the Indian Health Service (IHS).

Access to Data. Similarly, the Secretary is required to enter into data-sharing agreements with the Commissioner of Social Security, the Secretaries of the VA and DOD, and the Director of the IHS to help identify fraud, waste, and abuse, and allow DOJ access to these data.

Overpayments. This provision requires that overpayments be reported and returned within 60 days from the date of identification or by the date that the corresponding cost report is due (as applicable). In addition, the provision specifically ties such overpayments to the "retention of overpayments" language in the federal FCA.

This is a key provision because it establishes a general deadline for reporting and returning overpayments. Under the May 2009 amendments to the federal FCA, the retention of an overpayment is a specific basis for liability. With this provision, Congress has determinatively tied FCA liability to 60 days from the discovery of an overpayment. One question, however, is, "What constitutes identification of an overpayment?" Stated otherwise, when does the clock start ticking on the 60-day obligation? This is a very broad provision that could be read to include violations of Stark, anti-kickback, and other fraud and abuse provisions, as the violation of such laws may "disqualify" the underlying claim (creating an overpayment). For example, under Stark, the failure

to timely sign a lease between a physician and a hospital could disqualify all referrals made by that physician to the hospital and create an overpayment obligation under this provision.

National Provider Identifier. This section requires the Secretary to issue a regulation mandating that all Medicare, Medicaid, and CHIP providers include their NPI on enrollment applications.

Permissive Exclusions. This section adds a new permissive exclusion provision related to false statements provided on enrollment applications (to all federal health care programs). In addition, this section expands application of CMPs to individuals who order or prescribe an item or service, make false statements on applications or contracts to participate in a federal health care program, or who know of an overpayment and do not return the overpayment. Each violation is subject to CMPs of up to \$50,000.

Certain Charitable and Innocuous Contributions. The PPACA clarifies conditions and provides for rulemaking under which certain charitable or free goods can be offered.

Testimonial Subpoena Authority for Exclusion Cases. This section creates a new testimonial subpoena authority to be used by the OIG in exclusion actions.

Surety Bonds. This provision requires that the Secretary take into account the volume of billing for a DME supplier or HHA when determining the size of the surety bond. The Secretary can also impose this requirement on other providers and suppliers, depending on the level of risk presented by provider or supplier.

Criminal Health Care Fraud Laws, Including the Anti-Kickback Law. First, a violation of the Criminal Health Care Fraud Laws⁴³, including the anti-kickback law, is now a predicate action for violation of the federal FCA. Second, the Criminal Health Care Fraud Laws, including the anti-kickback law, has been amended to provide that a person need not have actual knowledge of the laws or specific intent to commit a violation of the laws.

The first provision settles the issue of whether a violation of the certain criminal health care laws, including the anti-kickback law, is a predicate violation of the federal FCA. Most courts have held that it is,⁴⁴ but some courts have limited application, for example, to providers who

⁴³ 42 U.S.C. § 1320a-7b.

⁴⁴ See, e.g., *McNutt ex rel. United States v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005) (holding that violation of the anti-kickback law and corresponding submission of claims for which government does not owe payment makes the claim false under the FCA); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d at 902 (holding that claimant submits a false or fraudulent claim under the FCA when he or she falsely certifies compliance with a federal statute or regulation); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) (holding that false certifications of compliance create liability under the FCA when certification is required to obtain government benefit); *United States ex rel. Pogue v. American Healthcorp*, 914 F. Supp. 1507, 1511 (M.D. Tenn. 1996) (holding that FCA liability attaches in situations where the claimant submits false records or engages in fraudulent conduct in order to receive payment).

have signed enrollment certifications that pledge compliance (to such laws).⁴⁵ It was in the late 1990s that the CMS-855 form began to require such a statement, and it is possible that all providers or suppliers with liability have not certified to compliance. Further, of course, there are numerous entities with potential liability under the anti-kickback law that are not enrolled as either a supplier or a provider. All entities would therefore now be subject to suit under the FCA and be subject to a potentially longer statute of limitations.

With regard to the second provision, the intent provisions in the statute have not been amended. Instead, the section has been appended to add the paragraph as follows:

(h) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

Because paragraph (h) is not an amendment but an addition, the "knowingly and willfully" language that describes that actual crime remains in the law. Courts have generally interpreted "willfully" to require proof of "specific intent." Therefore, these provisions would appear to conflict, and courts will likely be required to interpret the new language.

Payment Suspensions. This provision allows the Secretary to suspend payments to a provider or supplier pending a fraud investigation.

Health Care Fraud and Abuse Control (HCFAC) Account. This section increases funding for HCFAC by \$10 million each year for FYs 2011 through 2020, and provides for a permanent CPI adjustment to HCFAC, and also for Medicare Integrity Program (MIP) funding.

Medicare and Medicaid Integrity Programs. This provision requires contractors to provide statistics on activities, including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment.

Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank (Sec. 6403)

This section creates a national health care fraud and abuse data collection program for reporting certain adverse actions taken against health care providers, suppliers, and practitioners, and submits information on the actions to the National Practitioner Data Bank (NPDB). The Healthcare Integrity and Protection Data Bank (HIPDB) would be terminated and this information would be transferred to the NPDB.

⁴⁵ In addition, scholars have also argued that violations of the anti-kickback law cannot give rise to actions under the FCA. See John T. Boese and Beth C. McClain, "Why Thompson is Wrong: Misuse of the False Claims Act to Enforce the Anti-Kickback Act," 51 Ala. L. Rev. 1 (1999); Lisa Phelps, "Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violation to Support Civil False Claims Actions," 51 Vand. L. Rev. 1003 (1998).

Maximum Period for Submission of Medicare Claims Reduced to Not More than 12 Months (Sec. 6404)

Beginning January 2010, the maximum period for submission of Medicare claims would be reduced to not more than 12 months from the date of service. This new rule applies to all parts of Medicare.

Physicians Who Order Items or Services Required to be Medicare-Enrolled Physicians or Eligible Professionals (Sec. 6405)

Physicians who prescribe DME or home health services must be enrolled in the Medicare program. This requirement could be extended by regulation to other services.

Requirement for Physicians to Provide Documentation on Referrals to Programs at High Risk of Waste and Abuse (Sec. 6406)

The PPACA authorizes the Secretary to disenroll for up to one year a Medicare-enrolled physician or supplier that fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services, or referrals for other items and services, effective January 1, 2010. A requirement to maintain and provide access to such documentation also is added to the general Medicare provider enrollment requirements set forth at section 1866 of the SSA. Moreover, the PPACA extends the OIG's permissive exclusion authority to include individuals or entities that order, refer, or certify the need for health care services, but fail to provide adequate documentation to verify payment.

Face-to-Face Encounter with Patient Required Before Physicians May Certify Eligibility for Home Health Services or DME (Sec. 6407, 10605)

The PPACA requires physicians to document that they have had a face-to-face encounter (including through telehealth as permitted) with the Medicare or Medicaid beneficiary prior to issuing a certification for home health services, effective for certifications made after January 1, 2010. Section 10605 adds that the face-to-face encounter, in addition to being with the physician himself or herself, may also be with a nurse practitioner or clinical nurse specialist working in collaboration with the physician in accordance with state law, with a certified nurse-midwife as authorized by state law, or with a physician assistant under the supervision of the physician.

Likewise, the PPACA provides that as a condition of a written order for DME under Medicare, the physicians must document that the physician, physician assistant, nurse practitioner, or clinical nurse specialist has had a face-to-face encounter (including through telehealth as permitted) with the beneficiary during the six-month period preceding the written order, or other reasonable timeframe as determined by the Secretary.

The Secretary also is authorized to apply the face-to-face encounter requirement to other Medicare items and services based upon a finding that doing so would reduce the risk of fraud, waste, and abuse.

Enhanced CMP Penalties (Sec. 6408)

Under this provision, various CMPs are increased, including CMPs for persons who fail to grant the OIG timely access to documents, for the purpose of audits, investigations, evaluations, or other statutory functions. Also, persons who knowingly make, use, or cause to be made or used any false statement to a federal health care program, would be subject to a CMP of \$50,000 for each violation. The violations that could be subject to the imposition of sanctions and CMPs by the Secretary would include Part C MA plans or Part D plans that: (1) enroll individuals in an MA or Part D plan without their consent, (2) transfer an individual from one plan to another for the purpose of earning a commission, (3) fail to comply with marketing requirements and CMS guidance, or (4) employ or contract with an individual or entity that commits a violation. Penalties for Part C and Part D plans that misrepresent or falsify information would be increased to up to three times the amount claimed by a plan or plan sponsor based on the misrepresentation or falsified information.

Medicare Self-Referral Disclosure Protocol (Sec. 6409)

Within six months, the OIG will issue regulations to establish a self-disclosure protocol for violations of the Stark physician self-referral law.

In an Open Letter to Providers March 24, 2009, the Inspector General limited the application of the self-disclosure protocol to Stark violations that also had a colorable anti-kickback law violation; disclosures based solely on a Stark violation would no longer be accepted. Therefore, entities who discover potential Stark violations currently have no avenue for self-disclosure.

Adjustments to the Medicare DMEPOS Competitive Acquisition Program (Sec. 6410)

By way of background, under the DMEPOS competitive bidding program, only suppliers who are successful bidders will be eligible to furnish certain categories of DMEPOS to Medicare beneficiaries in certain geographic areas (with very limited exception). Successful bidders will be paid based on the median of the winning suppliers' bids for each of the selected items in the region, rather than the Medicare fee schedule or supplier bid amount. Competitive bidding is being phased in geographically and by product category. CMS conducted the first round of DMEPOS competitive bidding in 2007 in 10 geographic areas and for 10 product categories, and the program briefly went into effect in July 2008. Because of widespread concerns about how the program was implemented, however, MIPPA blocked round 1 and adopted a series of changes to the program. Under MIPPA, CMS was directed to conduct a new round 1 rebid in nine geographic areas in 2009, and conduct a second phase of bidding in 2011 in "an additional 70" of the largest metropolitan statistical areas.⁴⁶

⁴⁶ CMS conducted the round 1 rebid last year, and the agency is expected to announce winning bidders later this year, with contract prices set to go into effect January 1, 2011. For detailed background on the DMEPOS competitive

The PPACA requires the Secretary to expand the number of areas to be included in round 2 of the competitive bidding program from 79 to 100 of the largest MSAs. In addition, the PPACA requires (rather than permits) the Secretary to use information regarding payments determined under competitive bidding to adjust DMEPOS payments in areas outside of competitive bidding areas beginning in 2016. Likewise, for items furnished on or after January 1, 2016, the Secretary is directed to continue to adjust prices as additional information is obtained when new items are subject to competitive bidding or when contracts are recompeted.

Expansion of the Recovery Audit Contractor (RAC) program (Sec. 6411)

In the Tax Relief and Health Care Act of 2006, Congress required a permanent and national RAC program to be in place by January 1, 2010. This program, however, did not include Medicare Parts C and D, nor did it include state Medicaid programs. This provision expands the RAC program to Medicaid and to the other parts of the Medicare program.

The goal of the program is to identify improper payments to Medicare providers and suppliers, including underpayments and overpayments. In the demonstration project that occurred between 2005 and 2008, RAC audits resulted in more than \$900 million in overpayments being returned to the Medicare Trust Fund, and nearly \$38 million in underpayments returned to health care providers.

Community Mental Health Centers (Reconciliation Act Sec. 1301)

This section of the Reconciliation Act puts additional qualification standards on community mental health centers that provide Medicare partial hospitalization services. These facilities must now provide at least 40% of services to individuals who are not eligible for benefits under Medicare and restricts application of such programs that provide services in a patient's home or "inpatient or residential setting."

Medicare Prepayment Medical Review Limitations (Reconciliation Act Sec. 1302)

This provision repeals section 1874a(h) of the Social Security Act, which is a section regarding the conduct of prepayment review. This is a section of the Act that required prepayment reviews to be conducted under certain circumstances, for example, standard protocols developed by the Secretary. It also limited "non-random" prepayment reviews unless there is a likelihood of sustained or high level of payment error. Stated otherwise, these provider and supplier protections against random governmental audit and review have been eliminated.

bidding program, see <http://www.reedsmith.com/db/documents/hc0804.pdf>. For Reed Smith's ongoing reporting on this issue, see <http://www.healthindustrywashingtonwatch.com/tags/dmepos-competitive-bidding/>.

Funding to Fight Fraud, Waste and Abuse (Reconciliation Act Sec. 1304)

Section 1301 of the Reconciliation Act increases funding for the Health Care Fraud and Abuse Control Fund (HCFAC) by \$250 million over the next decade. The HCFAC program is designed to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse. This section also indexes funds to fight Medicaid fraud based on the increase in the CPI.

90-Day Period of Enhanced Oversight for Initial Claims of DME Suppliers (Reconciliation Act Sec. 1305)

In addition, section 1304 of the Reconciliation Act authorizes the Secretary to hold Medicare claims for up to 90 days for certain new DME suppliers. Specifically, effective January 1, 2011, if the Secretary determines that there is a significant fraud risk among suppliers furnishing certain types of DME or operating in certain geographic areas, the Secretary can withhold Medicare payment to such suppliers for 90 days after the date the supplier first submits a DME claim. According to a House Rules Committee analysis, this period would enable enhanced oversight of such claims.

Subtitle F—Additional Medicaid Program Integrity Provisions

Termination of Provider Participation under Medicaid if Terminated under Medicare or Other State Plan (Sec. 6501)

The PPACA requires states to terminate the enrollment of individuals or entities from their Medicaid programs if the individuals or entities were terminated from Medicare or another state's Medicaid program.

Medicaid Exclusion from Participation Relating to Certain Ownership, Control, and Management Affiliations (Sec. 6502)

Similar to the previous section, this provision requires Medicaid agencies to exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that: (1) has failed to repay overpayments during the period as determined by the Secretary; (2) is suspended, excluded, or terminated from participation in any Medicaid program; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.

Billing Agents, Clearinghouses, or Other Alternate Payees Required to Register under Medicaid (Sec. 6503)

This section of PPACA requires any agents, clearinghouses, or other alternate payees that submit claims on behalf of health care providers to register with the state and the Secretary in a

form and manner specified by the Secretary. This is yet another provision that deals with increased scrutiny of entities that participate in federal health care programs.

Miscellaneous additional provisions include the following:

- **Requirement to Report Expanded Set of Data Elements under Medicaid Management Information Systems (MMIS) to Detect Fraud and Abuse.** Requires states and Medicaid managed care entities to submit data elements from MMIS as determined necessary by the Secretary for program integrity, program oversight, and administration. MMIS is the claims-processing system that states are now using to manage Medicaid claims. (Sec. 6504)
- **Prohibition on Payments to Institutions or Entities Located Outside of the United States.** Prohibits states from making any payments for items or services provided under a Medicaid state plan or waiver to any financial institution or entity located outside of the United States. (Sec. 6505)
- **Overpayments.** Extends the period for states to repay overpayments to one year when a final determination of the amount of the overpayment has not been determined because of an ongoing judicial or administrative process. When overpayments as a result of fraud are pending, state repayments of the federal portion would not be due until 30 days after the date of the final judgment. (Sec. 6506)
- **Mandatory State Use of National Correct Coding Initiative.** Requires states to make their MMIS methodologies compatible with Medicare's national correct coding initiative (NCCI) that promotes correct coding and controls improper coding. (Sec. 6507)
- **General Effective Date.** The effective date is January 1, 2011. States may be required to amend state plans through legislation. (Sec. 6508)

Subtitle G—Additional Program Integrity Provisions

Prohibition on False Statements and Representations (Sec. 6601)

This provision of PPACA amends ERISA to address potential false statements in marketing materials regarding multiple employer welfare arrangements (MEWAs). Such false statements will result in criminal liability if the statements falsely represent a plan's financial solvency, benefits, or regulatory status.

Clarifying Definition (Sec. 6602)

This is an amendment to Title 18 of the U.S. Code to include the above-discussed ERISA false statement prohibition in the definition of a health care offense.

Development of Model Uniform Report Form (Sec. 6603)

To facilitate consistent reporting by private health plans of suspected cases of fraud and abuse, a model uniform reporting form will be developed by the National Association of Insurance

Commissioners, under the direction of the Secretary. This is another data-sharing and coordination provision intended to earlier identify fraudulent schemes and actors.

Applicability of State Law to Combat Fraud and Abuse (Sec. 6604)

PPACA directs the Department of Labor (DOL) to adopt regulatory standards and/or issue orders to prevent fraudulent MEWAs from escaping liability for their actions under state law by claiming that state law enforcement is preempted by federal law. Stated otherwise, this provision attempts to address potential preemption issues under ERISA via DOL regulation.

Enabling the DOL to Issue Administrative Summary Cease-and-Desist Orders and Summary Seizures Orders Against Plans in Financially Hazardous Condition (Sec. 6605)

DOL is authorized to issue "cease and desist" orders to temporarily shut down operations of ERISA plans conducting fraudulent activities or posing a serious threat to the public, until hearings can be completed. If it appears that a plan is in a financially hazardous condition, the agency may seize the plan's assets.

MEWA Plan Registration with the DOL (Sec. 6606)

MEWAs will be required to file their federal registration forms, and thereby be subject to government verification of their legitimacy, before enrolling anyone.

Permitting Evidentiary Privilege and Confidential Communications (Sec. 6607)

PPACA permits the DOL to allow confidential communication among public officials relating to investigation of fraud and abuse.

Health Care Fraud Enforcement (Sec. 10606)

This section of PPACA requires the U.S. Sentencing Commission to review and amend the federal sentencing guidelines and policy statements applicable to persons convicted of federal health care offenses.

This section would deem existing certain criminal offenses to be "federal health care fraud offenses" under the U.S. Criminal Code. Similarly, section 6602 of PPACA also contains language to classify certain criminal ERISA violations as a "federal health care offense." By defining a particular offense as a "federal health care offense," convictions for violations of these listed statutes may be punishable by longer prison terms and/or higher fines. In addition to the ERISA provisions, the new federal health care offenses would include the anti-kickback statute, section 1349 of the U.S. Criminal Code (attempting or conspiring to commit a criminal offense), and section 301 of the federal Food, Drug, and Cosmetic Act.

Section 10606 also extends the general criminal health care fraud statute at 18 U.S.C. section 1347 to add the same language added to 42 U.S.C. § 1320a-7b by section 6401 of PPACA (*see discussion infra*).

Subtitle H—Elder Justice Act (EJA)

The EJA, which amends the Social Security Act to establish an elder justice program under Title XX, was first introduced six years ago as a stand-alone bill and has finally been enacted as part of the PPACA. The EJA establishes an Elder Justice Coordinating Council within the Office of the Secretary of HHS, comprised of federal agencies with responsibilities for programs that affect the elderly; its purpose is to coordinate elder justice activities across the federal government. The EJA also establishes an Advisory Board on Elder Abuse, Neglect, and Exploitation, which will be comprised of 27 members appointed by the Secretary. The goal of the Advisory Board is to create short- and long-term multidisciplinary strategic plans for the development of the field of elder justice, and to make recommendations to the Elder Justice Coordinating Council. Within 18 months, and annually thereafter, the Advisory Board will prepare a report for the Coordinating Council and relevant committees of Congress on the status of elder justice activities and the Advisory Board's recommendations.

The EJA also does the following:

- Directs the Secretary to make grants to establish and operate four stationary and six mobile forensic centers to develop forensic expertise on elder abuse
- Authorizes the Secretary to make grants to LTC facilities for the purpose of assisting such entities in offsetting the costs related to purchasing, leasing, developing, and implementing certified EHR technology designed to improve patient safety and reduce adverse events and health care complications resulting from medication errors
- Requires the Secretary to adopt electronic standards for the exchange of clinical data by LTC facilities, including, where available, standards for messaging and nomenclature
- Requires the Secretary to carry out activities to provide incentives for individuals to train for, seek, and maintain employment providing direct care in LTC facilities
- Establishes an adult protective services grant program through which grants will be distributed to states to enhance adult protective services provided by states and local governments
- Establishes a demonstration grant program to award grants to states to conduct demonstration programs on such matters as training for the purpose of detecting elder abuse and methods to detect financial fraud
- Authorizes the Secretary to provide grants to entities with expertise and experience in LTC facilities or LTC ombudsman programs, to improve the capacity of state LTC ombudsman programs, and to conduct pilot programs with state LTC ombudsman offices
- Directs the Secretary to enter into a contract with an entity to establish and operate a National Training Institute for federal and state surveyors, to provide and improve the

training of surveyors with respect to investigating allegations of abuse, neglect, and misappropriation of property

- Directs the Secretary to make grants to state agencies that perform surveys of SNFs or nursing facilities, to be used to design and implement complaint investigations systems
- Instructs the Secretary to conduct a study on the establishment of a national nurse aide registry

Significantly, and effective upon enactment, the EJA requires each individual owner, operator, employee, manager, agent, or contractor of an LTC facility that receives at least \$10,000 in federal funds annually to report to the Secretary and one or more local law enforcement entities, any reasonable suspicion of a crime against anyone who is a resident of, or is receiving care from, the facility. Steep penalties can be imposed on individuals for failure to report within specified time frames. The EJA also contains whistleblower protections for facility employees, and provides for additional penalties for retaliation. In addition, each LTC facility must post conspicuously in an appropriate location a sign, in a form to be specified by the Secretary, specifying the rights of employees under the EJA. Such sign shall include a statement that an employee may file a complaint with the Secretary against an LTC facility that violates the law, and information regarding how to file such a complaint.

Terms such as "abuse," "elder justice," "exploitation" and "neglect," among others, are specifically defined in the new law.

Subtitle I—Sense of the Senate Regarding Medical Malpractice

Medical Malpractice Provisions (Sec. 6801, 10607, 10608)

In a modest concession to some members of Congress who view tort reform as a basis to control escalating health care costs, the PPACA includes a statement that "health care reform presents an opportunity to address issues related to medical malpractice and medical liability insurance." The statute states that Congress should consider establishing a state demonstration program to evaluate alternatives to the current civil litigation system.

Section 10607 authorizes the Secretary to award demonstration grants to states of up to \$500,000 per year for five years beginning with FY 2011 for the development, implementation and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations. These models would be required to promote a reduction of health care errors by encouraging the collection and analysis of patient safety data by organizations that engage in efforts to improve patient safety and quality of health care. Possible approaches are health care courts or panels dedicated to hearing these types of cases. Notably, patients would be able to opt-out of these alternatives at any time. Other specific criteria apply. Unlike earlier versions of the legislation, there is no specific prohibition from qualification if a state limits attorneys' fees or imposes caps on damages. A federal review panel, chaired by the Comptroller General or his designee from the GAO, will

review the grant applications. Once states undertake these alternative dispute resolution processes, the Secretary would be required to conduct an evaluation to determine the effectiveness of the alternatives. MedPAC and the Medicaid and CHIP Payment and Access Commission are also charged with assessing the alternatives to tort litigation developed under the state grants to determine the impact on Medicare, Medicaid and CHIP programs, respectively, and their beneficiaries, and to report to Congress by December 31, 2016. Section 10608 amends the PHS to extend to free clinics the protections from liability contained in the Federal Tort Claims Act. Specifically, the protection extends liability protection to an officer, governing board member, employee, or contractor of a free clinic in providing services for the free clinic. The provision applies to any act or omission that occurs after the date of enactment.

Title VII—Improving Access to Innovative Medical Therapies

Subtitle A—Biologics Price Competition and Innovation

Abbreviated Approval Pathway for Follow-On Biologics (Sec. 7001-7003)

The PPACA amends the PHSA to establish, for the first time, an approval pathway for generic versions of biologics ("follow-on" or "biosimilars") licensed under section 351 of the PHSA, which may provide more affordable alternatives to branded ("pioneer") biologics. The legislation amends section 351(i) of the PHSA to provide, among other things, 12 years of exclusivity to the manufacture of a pioneer biologic (i.e., the branded biologic reference product). The PPACA defines a biosimilar product as a product that is "highly similar" to a reference product "notwithstanding minor differences in clinically inactive components," and for which there are "no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product."

Biosimilar Approval Process (Sec. 7002)

Biosimilar Applications and Interchangeability

Biosimilar applications may not be submitted until four years after the date on which the reference product was approved. Each application must include information demonstrating that the new product is biosimilar to its branded biologic reference product based on:

- Analytical studies demonstrating that the biological product is "highly similar to the reference product notwithstanding minor differences in clinically inactive components"
- Animal studies, including the assessment of toxicity
- A clinical study or studies ("including the assessment of immunogenicity and pharmacokinetic or pharmacodynamics") that are sufficient to demonstrate "safety, purity, and potency" in one or more conditions of use for which the reference product is licensed and intended to be used, and for which licensure is sought for the biosimilar.

The PPACA gives the Secretary the flexibility to waive any of these studies.

Although not required by the PPACA, applications for biosimilar products may include information demonstrating that the biosimilar product is "interchangeable" with its reference product. An interchangeable product is one that is biosimilar to the reference product and "can be expected to produce the same clinical result" as the reference product in any given patient.⁴⁷ For products that are administered more than once to an individual, an interchangeable determination is possible only if "the risk in terms of safety or diminished efficacy of alternating or switching" between the products is not greater than "the risk of using the reference product without such alteration or switch."

⁴⁷ Sec. 7002(a), amending § 351 of the PHSA (42 U.S.C. § 262(k)(3), (4)).

In an effort to consolidate the approval and regulation of biosimilars under the PHSA, the PPACA requires applications for biosimilar products to be submitted under section 351 of the PHSA except when (1) the product is part of a class of products where an approved application under section 505 of the FDCA existed on the date the PPACA became law, and (2) the biosimilar application is submitted for approval within 10 years after the date the PPACA became law. Further, a biosimilar application may not be submitted under section 505 of the FDCA if another biological product is approved under section 351 of the PHSA. The PPACA also deems all approved applications for biological products under section 505 of the FDCA to be licenses under section 351 of the PHSA 10 years after the date the PPACA became law.

Exclusivity

The PPACA prohibits the approval of an application as either biosimilar or interchangeable until 12 years from the date on which the reference product is first approved, or 18 months if pediatric studies are conducted. These exclusivity provisions do not apply to a license for, or approval of, a supplement to the reference product, including a change that results in "a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength" or a modification to the structure of the product that does not result in a change in safety, purity, or potency. The PPACA also extends the exclusivity time frame for a biological product designated for a rare disease or condition.⁴⁸

A biosimilar that is deemed "interchangeable" will be granted exclusivity until the earlier of (1) one year after the first commercial marketing of the product as interchangeable; (2) 18 months after a final court decision on all patent suits in an action against the applicant, or the dismissal of such suit with or without prejudice; (3) 42 months after approval of the initial application if the applicant has been sued; or (4) 18 months after approval of the initial application if the applicant has not been sued.

Risk Evaluation and Mitigation Strategy

The PPACA permits the Secretary to require applicants to submit a proposed risk evaluation and mitigation strategy (REMS) as part of the application if the Secretary determines that a REMS is necessary to ensure that the benefits of a drug outweigh its risks. FDA was granted authority to require REMS under the Food and Drug Administration Amendments Act of 2007.

⁴⁸ These products are granted orphan drug designation under section 526 of the FDCA for a rare disease or condition. See 21 U.S.C. § 360bb.

Guidance Documents

The PPACA permits the Secretary to issue guidance documents about the biosimilar approval process, and requires that all product class-specific guidance include a description of the criteria the Secretary will use to determine whether a product is "highly similar" (i.e., biosimilar) to, and – if available when the Secretary issues the guidance – interchangeable with, a reference product in the class. The issuance (or non-issuance) of a guidance document will not preclude the review of, or action on, an application. The Secretary may, however, indicate in a guidance document that the current state of science and the Secretary's experience with respect to certain products or product classes (not including recombinant proteins) prevent the Secretary from approving any applications related to such products or product classes.

Patent Issues (Sec. 7002)

The PPACA sets forth provisions governing the exchange of confidential information related to patents for biological products, requires good faith negotiations between the reference product sponsor and an applicant, and sets forth a complicated scheme for patent infringement lawsuits. The PPACA requires each applicant to provide to the reference product sponsor and patent owner(s) "confidential access to the application" and any other information the applicant determines, "in its sole discretion, to be appropriate" for the sole and exclusive purpose of determining, with respect to each patent related to the reference product, whether a claim of patent infringement could be reasonably asserted for the biosimilar product (amending section 351 of the PHSA (42 U.S.C. § 262(l)(1)(B))). The PPACA requires the reference product sponsor and applicant to follow a negotiation process before commencing patent infringement lawsuits. This process has six major steps.

- **Notice.** When the FDA notifies an applicant that the application has been accepted for review, the applicant must provide the reference product sponsor a copy of the application and "such other information that describes the process or processes used to manufacture" the biosimilar. A sponsor may also provide additional information requested by or on behalf of the reference product sponsor.
- **Sponsor Patent List.** No later than 60 days after the receipt of the application, the reference product sponsor must provide the applicant with a list of patents for which the sponsor believes a claim of patent infringement could reasonably be asserted by the sponsor, and an identification of the patents on this list that the sponsor (or patent owner) would be prepared to license to the applicant.
- **Applicant Response.** No later than 60 days after receipt of the sponsor's patent list, the applicant must provide to the sponsor, with respect to each patent identified by the sponsor: (1) a detailed statement that the patent claim is invalid, unenforceable, or will not be infringed by the commercial marketing of the biosimilar ("detailed statement"); or (2) a statement that the applicant does not intend to begin commercial marketing of the biosimilar before the date that the patent expires. Further, the applicant must respond

to any indication that the sponsor is prepared to license specific patents to the applicant. The applicant may provide the sponsor a list of patents for which the applicant believes a claim of patent infringement is valid.

- **Sponsor Response.** No later than 60 days after receipt of the applicant's patent list and detailed statement, the sponsor must provide a comprehensive response disputing the applicant's detailed statement.
- **Negotiation and Litigation.** The applicant must engage in good faith negotiations to agree on a final and complete list of patents to be litigated. If the parties reach agreement within 15 days of beginning negotiations, the reference product sponsor must bring an action for patent infringement within 30 days after such agreement. If the parties do not reach agreement within 15 days, the applicant must provide the sponsor with a final list of patents the applicant believes are invalid, unenforceable, or will not be infringed by the marketing of the product. The parties have five days to consider this list before simultaneously exchanging a final list of patents that each respective party believes should be subject to an action for patent infringement. The reference product sponsor has 30 days to bring an action for patent infringement after this exchange. Applicants must submit to the Secretary copies of any patent complaints filed by the product sponsor within 30 days of receipt of service. The Secretary will publish in the *Federal Register* a notice of the receipt of the complaint(s).
- **Commercial Marketing Notice and Declaratory Judgment Actions.** Applicants must notify reference product sponsors no later than 180 days before the date of the first commercial marketing of a biosimilar product. Unless the applicant failed to comply with certain provisions of the PPACA (e.g., failing to provide the product sponsor with a copy of the biosimilar application within 20 days of submitting the application to the Secretary for review), the reference product sponsor must wait until it receives the commercial marketing notice before bringing a declaratory judgment action.

PPACA includes additional penalties for non-compliance with this negotiation and litigation process. A product sponsor may, for example, be prohibited from filing a patent infringement claim if the patent was not included in the initial list of patents exchanged between the parties when they began negotiations.

User Fees and Savings (Sec. 7002-7003)

Beginning not later than October 1, 2010, the PPACA requires that the Secretary develop recommendations for the goals for the review process of biosimilar applications; collect and evaluate data regarding the cost of reviewing such applications; and determine whether to alter the user fee applicable to such applications. The PPACA urges Congress to authorize the collection of user fees as of October 1, 2012.

Subtitle B—More Affordable Medicines for Children and Underserved Communities

Public Health Service Section 340B Program Amendments (Sec. 7101-7103, Reconciliation Act Sec. 2302)

The Public Health Service (PHS) section 340B drug discount program (42 U.S.C. § 256B) requires manufacturers of "covered outpatient drugs" to charge specified "covered entities" no more than a maximum discounted price that is equal to the difference between a drug's Medicaid AMP and the average total Medicaid rebate. Covered entities include a variety of entities receiving grants from the PHS to provide services to medically underserved populations, as well as certain disproportionate share hospitals.

In addition to the fact that PHS discounts are likely to increase as a result of the amendments to the Medicaid rebate statute described above (e.g., the modifications to AMP, the increase in the minimum rebate percentage, and the modifications to the additional rebate formula for line extensions of brand name drugs), PPACA further extends the 340B program to additional covered entities, and authorizes significant new oversight of the program. However, because of amendments in the Reconciliation Act, the statute does not extend 340B program discounts to covered entities' purchases of products for inpatient use.

Expanded classes of covered entities. PPACA authorizes Medicare PPS-exempt children's hospitals and cancer hospitals that meet disproportionate share eligibility criteria, critical access hospitals, and rural referral centers or sole community hospitals with disproportionate share adjustments of greater than or equal to 8%, to qualify as "covered entities." However, these entities will not be able to purchase FDA-designated orphan drugs at PHS discounted prices. These provisions take effect January 1, 2010.

Program Integrity. The PPACA also contemplates a significant expansion with respect to administrative oversight of the 340B program, which has historically been relatively modest. These provisions are subject to appropriations.

First, the PPACA authorizes the PHS to develop a system to verify the accuracy of ceiling prices calculated and charged by manufacturers to covered entities. Second, PHS must establish procedures for manufacturers to issue refunds to covered entities in cases of overcharges (including those resulting from both routine adjustments to Medicaid pricing data and non-routine overcharge situations). Third, the statute authorizes PHS to develop an Internet website through which covered entities may obtain the PHS prices. Fourth, the statute contemplates a system to report additional rebates that may lower PHS prices and to provide credits to covered entities in those instances. Fifth, the PHS must audit both manufacturers and wholesalers with respect to program compliance. Sixth, the statute would authorize civil money penalties of up to \$5,000 against manufacturers that knowingly and intentionally overcharge covered entities.

PPACA also contemplates improvements for covered entity compliance and identification, including a system to update current information, the development of a unique identifier, and the imposition of sanctions where a covered entity diverts products for non-covered uses or otherwise fails to comply with program requirements.

Finally, but perhaps most importantly, PPACA requires PHS to establish administrative dispute resolution (ADR) procedures to address claims of both manufacturer and covered entity noncompliance. These regulations are to be promulgated within 180 days of the enactment of the statute. These procedures would include discovery from manufacturers and third parties by covered entities, and would permit the hearing entity to consolidate claims from multiple claimants, to allow joint claims by covered entities, and to allow associations to assert claims rather than the covered entities themselves. Manufacturers should consider appropriate steps now to prepare for potential ADR claims, as some covered entities and their trade associations have been relatively aggressive in such matters.

Title VIII—CLASS Act

Establishment of National Voluntary Insurance Program for Purchasing 'Community Living Assistance Services and Support' (CLASS Act) (Sec. 8002)

The CLASS Act was a pet project of the late Sen. Ted Kennedy (D-Mass.), who promoted the idea of a premium-funded long-term care insurance program that would fill the gaps left by the traditional Medicare and private insurance coverage that focused on higher acuity patients. In simple terms, this is an insurance program for individuals who may need some assistance as they age, but do not need more intense services such as those provided in a nursing home. It is intended that beneficiaries can use the cash benefit paid under CLASS to purchase caregiver services – perhaps someone to help prepare a meal or to do grocery shopping. The CLASS Act is not intended to replace other long-term care benefits, but to supplement those benefits and allow someone who is elderly or disabled to remain independent for a longer term, possibly saving the government money through lower utilization of traditional sub-acute coverage.

The program is financed through monthly premiums paid by voluntary payroll deductions. Working adults will be automatically enrolled in the program, unless they choose to opt-out.

Individuals receive a cash benefit based on degree of disability or impairment averaging no less than \$50 per day. The Secretary will set the benefit amount relative to the functional limitation.

There is a five-year vesting period for eligibility of benefits. The Secretary is required to develop an actuarially sound benefit plan that ensures solvency for 75 years, and premiums will be set by regulation. Actuarial support for the Act is crucial as it was heavily criticized by legislators as fiscally unsound; while CBO scored the provision to reduce the budget deficit by \$74 billion over 10 years, the vesting provision means that premiums will be paid immediately, but no benefits will be paid until year six. As this is a voluntary insurance plan, no taxpayer monies are intended to be utilized to fund the program.

Title IX—Revenue Provisions

Subtitle A—Revenue Offset Provisions

Additional Requirements for Charitable Hospitals (Sec. 9007)

The PPACA imposes new requirements for charitable hospitals. To satisfy the tax-exempt requirements under IRS Code section 501(c)(3), the organization must conduct a community health needs assessment every two years, develop a financial assistance policy, impose limitations on emergency or other medically necessary care provided to individuals eligible for financial assistance, and not engage in extraordinary collection actions against an individual without first determining if the individual would be eligible for financial assistance. Organizations failing to satisfy the community health assessment requirement may be subject to excise taxes of \$50,000.

These provisions are generally effective for taxable years beginning after March 23, 2010. The provisions relating to the community health needs assessment apply to taxable years beginning after March 23, 2012, and the excise tax provisions apply to failures occurring after March 23, 2010.

Pharmaceutical Manufacturer and Importer 'Industry Fees' (Sec. 9008, Reconciliation Act Sec. 1404)

Beginning in 2011, manufacturers and importers of branded prescription drugs and biologics⁴⁹ will be assessed an annual "fee." The amount of the aggregate industry fees is specified by the statute (\$2.5 billion in 2011, \$3 billion in 2012-16, \$3.5 billion in 2017, \$4.2 billion in 2018, and \$2.8 billion each year thereafter). These fees are to be transferred to the Medicare Part B trust fund, and are not deductible for income tax purposes. The civil action procedures for excise taxes apply to these fees, although the fees are not explicitly characterized as excise taxes for purposes other than non-deductibility.

The Secretary of the Treasury determines each manufacturer or importer's share of the aggregate fee based on the ratio of (1) its "branded prescription drug sales" in a taxable year to specified government programs, to (2) that of the aggregate "prescription drug sales" of all manufacturers and importers to such programs in such year (i.e., roughly based on its market share). However, the determination of a manufacturer's or importer's "branded prescription drug sales" is subject to several important statutory provisions. First, such sales include sales of branded drugs and biologics, but not orphan drugs. Second, PPACA specifies primary (though not exclusive) source data for the Secretary to consider when determining such "branded

⁴⁹ The statute does not appear to contain an exemption for vaccines. Nor does the statute specify whether combination products will be considered to represent "drugs and biologics" for purposes of the pharmaceutical industry fees or medical devices for purposes of the medical device excise taxes described below.

prescription drug sales." This data includes: (1) Medicare Part D utilization and per unit ingredient costs, net of manufacturer discounts; (2) Medicare Part B utilization and average sales prices; (3) Medicaid utilization and per-unit ingredient costs net of Medicaid rebates and state supplemental rebates; (4) VA purchases and costs; and (5) DOD purchases of costs and TRICARE retail utilization and per-unit ingredient costs, net of manufacturer refunds. In other words, branded prescription drug "sales" are not actually determined based on manufacturer sales revenue, but rather on government net dispensing costs.⁵⁰ Third, all manufacturers' or importers' branded prescription drug sales are not weighted equally in the calculation. Instead, larger manufacturers' sales count in full, and only a portion of smaller manufacturers' sales count according to the following table:

Manufacturer Sales	Portion of Sales Counting in the Calculation
Up to \$5 million	0%
>\$5 million up to \$125 million	10%
>\$125 million up to \$225 million	40%
>\$225 million up to \$400 million	75%
>\$400 million	100%

The statute also specifies that certain Internal Revenue Code control group tests will be applied for purposes of determining the aggregate scope of a manufacturer's or importer's sales, and establish joint and several liability among entities within the control group. Although exceptions may exist, a "control group" is generally determined through ownership of value of voting shares in a corporation, or partnership or capital interest in a partnership, in most cases above certain thresholds of percentage ownership, including direct or indirect ownership, and ownership deemed to exist through ownership of an option for the shares or interest.

Aside from the obvious financial implications of these fees, they may also have implications with respect to corporate and deal structures, product launches, and future and existing license agreements. For example, manufacturers might wish to consider the implications of various business and ownership structures under the control group tests specified in the statute. Second, manufacturers – particularly smaller new manufacturers – might consider whether the timing of a product launch of new products (e.g., at the end of a taxable year) might defer or minimize liability. Third, with respect to licensing and royalty agreements, it is not entirely clear whether the "fees" should be viewed as taxes, overhead costs, reductions in revenue, or user fees for purposes of "net sales" or other royalty calculation mechanisms. This issue can be addressed prospectively through specific language, but may raise potential disputes under

⁵⁰ It bears note that most of the government utilization and dispensing cost data under these programs will be compiled on the basis of product NDCs. Thus, while the statute is not explicit in this regard, it is possible that the government will at least in the first instance deem the "manufacturer" of a product to be the entity whose NDC labeler code is on the product.

existing agreements where the calculation clauses do not specifically contemplate these fees. Fourth, if manufacturer's sales are attributed to entities on the basis of NDC labeler codes, the parties to product disposition transactions should pay careful attention to the implications of existing inventory bearing the seller's labeler code.

Medical Device Excise Taxes (Sec. 9009, Reconciliation Act Sec. 1405)

PPACA established similar "industry fees" applicable to medical device manufacturers and importers, but the Reconciliation Act replaced these provisions with a simpler excise tax, effective for sales on or after January 1, 2013. Specifically, manufacturers, producers, and importers of taxable medical devices must pay as an excise tax 2.3% of the price for which the devices are sold. "Taxable medical devices" generally include devices intended for human use, except for (1) eyeglasses, (2) contact lenses, (3) hearing aids, and (4) other devices determined by the Secretary of the Treasury to be purchased by the general public at retail for individual use.⁵¹ Again, the statute does not specifically address the treatment of combination products. The statute also limits certain exemptions from tax under sections 4221 and overpayment recoveries under section 6416 of the Internal Revenue Code for sales for supplying vessels or aircraft, to state or local governments, to nonprofit educational institutions, and blood collection organizations.

⁵¹ Note that an earlier version of the Reconciliation Act would have exempted Class I medical devices from this tax, but the final version did not include an exemption for Class I devices.

Conclusion

Implementation of the PPACA will present both challenges and opportunities for the health care/life sciences industry in the coming years. Reed Smith will be closely monitoring the regulatory and subregulatory guidance issued as a result of the new law, and we will be reporting on major developments on our policy blog, www.healthindustrywashingtonwatch.com. We also look forward to working together with our clients to develop and implement strategies to respond to enactment of the PPACA, from its new Medicare reimbursement policies to enhanced compliance requirements. Please feel free to contact us if you have questions or if you need additional information.

About Reed Smith

Reed Smith is a global relationship law firm with nearly 1,600 lawyers in 22 offices throughout the United States, Europe, Asia and the Middle East. Founded in 1877, the firm represents leading international businesses, from Fortune 100 corporations to mid-market and emerging enterprises. Its lawyers provide litigation services in multi-jurisdictional matters and other high-stakes disputes; deliver regulatory counsel; and execute the full range of strategic domestic and cross-border transactions. Reed Smith is a preeminent advisor to industries including financial services, life sciences, health care, advertising, technology, media, shipping, energy trade and commodities, real estate, manufacturing, and education. For more information, visit www.reedsmith.com.

This *Alert* is presented for informational purposes only and is not intended to constitute legal advice.

© Reed Smith LLP 2010. All rights reserved.

"Reed Smith" refers to Reed Smith LLP, a limited liability partnership formed in the state of Delaware.

Contributors

Elizabeth Carder-Thompson
+1 202 414 9213 (Washington)
ecarder@reedsmith.com

Cynthia A. Alcantara
+1 703 641 4306 (Falls Church)
calcantara@reedsmith.com

Laurie S. DuChateau
+1 412 288 3004 (Pittsburgh)
lduchateau@reedsmith.com

Scot T. Hasselman
+1 202 414 9268 (Washington)
shasselman@reedsmith.com

Julia Krebs-Markrich
+1 703 641 4232 (Falls Church)
jkrebs-markrich@reedsmith.com

Kathleen H. McGuan
+1 202 414 9278 (Washington)
kmcguan@reedsmith.com

Lorin E. Patterson
+1 703 641 4368 (Falls Church)
lpatterson@reedsmith.com

Steven B. Roosa
+1 609 514 5983 (Princeton)
sroosa@reedsmith.com

Nancy A. Sheliga
+1 804 344 3439 (Richmond)
nsheliga@reedsmith.com

Carol C. Loepere
+1 202 414 9216 (Washington)
cloepere@reedsmith.com

Brandy C. Canady
+1 703 641 4208 (Falls Church)
bcanady@reedsmith.com

Jennifer A. Goldstein
+1 202 414 9237 (Washington)
jgoldstein@reedsmith.com

Robert J. Hill
+1 202 414 9402 (Washington)
rhill@reedsmith.com

Areta L. Kupchyk
+1 202 414 9362 (Washington)
akupchyk@reedsmith.com

Joseph W. Metro
+1 202 414 9284 (Washington)
jmetro@reedsmith.com

Jacqueline B. Penrod
+1 215 851 8275 (Philadelphia)
jpenrod@reedsmith.com

Amie E. Schaadt
+1 215 851 8106 (Philadelphia)
aschaadt@reedsmith.com

Errin E. Simpkins
+1 202 414 9247 (Washington)
esimpkins@reedsmith.com

Debra McCurdy
+1 703 641 4283 (Falls Church)
dmccurdy@reedsmith.com

Gail L. Daubert
+1 202 414 9241 (Washington)
gdaubert@reedsmith.com

Thomas W. Greeson
+1 703 641 4242 (Falls Church)
tgreeson@reedsmith.com

Catherine A. Hurley
+1 202 414 9229 (Washington)
churley@reedsmith.com

Kevin M. Madagan
+1 202 414 9236 (Washington)
kmadagan@reedsmith.com

Elizabeth D. O'Brien
+1 202 414 9289 (Washington)
eobrien@reedsmith.com

Paul W. Pitts
+1 415 659 5971 (San Francisco)
ppitts@reedsmith.com
Jamie L. Schreiber
+1 202 414 9262 (Washington)
jschreiber@reedsmith.com

Karl A. Thallner Jr.
+1 215 851 8171 (Philadelphia)
kthallner@reedsmith.com

If you have questions or would like additional information on the material covered in this Alert, please contact one of the contributors or the Reed Smith lawyer with whom you regularly work.

Appendix A – Glossary of Terms

- **ACO** - Accountable Care Organization
- **ADR** - Alternative Dispute Resolution
- **AHRQ** - Agency for Healthcare Research and Quality
- **AKL** - Anti-Kickback Law
- **AMP** - Average Manufacturer Price
- **ARRA** - American Recovery and Reinvestment Act of 2009
- **ASC** - Ambulatory Surgery Center
- **BBA** - Balanced Budget Act of 1997
- **CAN** - Cures Acceleration Network
- **CBO** - Congressional Budget Office
- **CDC** - Centers for Disease Control and Prevention
- **Center** - Center for Quality Improvement and Patient Safety
- **CHIP** - Children's Health Insurance Program
- **CHIPRA** - Children's Health Insurance Program Reauthorization Act 2009
- **CIA** - Corporate Integrity Agreement
- **CLASS Act** - Community Living Assistance Services and Support
- **CMI** - Center for Medicare and Medicaid Innovation
- **CMP** - Civil Monetary Penalty
- **CMS** - Centers for Medicare & Medicaid Services
- **Commission** - National Health Care Workforce Commission
- **CO-OP** - Consumer Operated and Oriented Plan
- **CPI** - Consumer Price Index
- **CY** - Calendar Year
- **DGME** - Direct Graduate Medical Education
- **DME** - Durable Medical Equipment
- **DMEPOS** - Durable Medical Equipment, Prosthetics, Orthotics and Supplies
- **DOD** - Department of Defense
- **DOL** - Department of Labor
- **DRA** - Deficit Reduction Act of 2005
- **DRG** - Diagnosis Related Group
- **DSH** - Disproportionate Share Hospitals
- **DXA** - Dual-energy X-ray Absorptiometry
- **EHR** - Electronic Health Record
- **EJA** - Elder Justice Act
- **ERISA** - Employee Retirement Income Security Act
- **ESI** - Employer-Sponsored Insurance
- **ESRD** - End Stage Renal Disease
- **FCA** - False Claims Act
- **FDA** - Food and Drug Administration
- **FDCA** - Food, Drug, and Cosmetic Act
- **FMAP** - Federal Medical Assistance Percentage
- **FPL** - Federal Poverty Level
- **FQHC** - Federally Qualified Health Centers
- **FUL** - Federal Upper Limit
- **FY** - Fiscal Year
- **GAO** - Government Accountability Office
- **GPCI** - Geographic Practice Cost Index
- **GPO** - Group Purchasing Organization
- **HCAHPS** - Hospital Consumer Assessment of Healthcare Providers and Systems
- **HCBS** - Home and Community Based Services
- **HCFAC** - Health Care Fraud and Abuse Control
- **HHA** - Home Health Agency
- **HHS** - Department of Health and Human Services
- **HIPAA** - Health Insurance Portability and Accountability Act
- **HIPDB** - Healthcare Integrity and Protection Databank
- **HPSA** - Health Professional Shortage Area
- **HRSA** - Health Resources and Services Administration
- **IDR** - Integrated Data Repository
- **IHS** - Indian Health Service
- **IME** - Indirect Medical Education
- **IOM** - Institute of Medicine
- **IPAB** - Independent Payment Advisory Board
- **IPPS** - Inpatient Prospective Payment System
- **IRFs** - Inpatient Rehabilitation Facilities
- **LIS** - Low-Income Subsidies
- **LTCH** - Long-Term Care Hospital
- **MACPAC** - Medicaid and CHIP Payment and Access Commission
- **MA** - Medicare Advantage

- **MAO** – Medicare Advantage Organization
- **MA-PD** - Medicare Advantage Prescription Drug Plans
- **MA-SNP** - Medicare Advantage Special Needs Plans
- **MCO** - Managed Care Organization
- **MDH** - Medicare-Dependent Hospital
- **MDS** - Minimum Data Set
- **MedPAC** - Medicare Payment Advisory Commission
- **MEWA** - Multiple Employer Welfare Arrangements
- **MIF** - Medicaid Improvement Fund
- **MIP** - Medicare Integrity Program
- **MIPPA** - Medicare Improvements for Patients and Providers Act of 2008
- **MMA** - Medicare Prescription Drug, Improvement and Modernization Act of 2003
- **MMIS** - Medicaid Management Information System
- **MMSEA** - Medicare, Medicaid, and SCHIP Extension Act of 2007
- **MOCP** - Maintenance of Certification Program
- **MOE** - Maintenance of Effort
- **MTM** - Medication Therapy Management
- **NCCI** – National Correct Coding Initiative
- **NDA** – New Drug Application
- **NDC** - National Drug Code
- **NHSC** - National Health Service Corps
- **NIH** – National Institutes of Health
- **NPDB** - National Practitioner Data Bank
- **NQF** - National Quality Forum
- **OACT** - Office of the Actuary
- **Office** - Federal Coordinated Health Care Office
- **OIG** - Office of Inspector General
- **OPPS** – Outpatient Prospective Payment System
- **OT** - Occupational Therapy
- **PBM** - Pharmacy Benefits Manager
- **PCORI or Institute** - Patient–Centered Outcomes Research Institute
- **PDP** - Prescription Drug Plan
- **PhRMA** - Pharmaceutical Research and Manufacturers of America
- **PHS** - Public Health Service
- **PHSA** - Public Health Service Act
- **PPACA** - Patient Protection and Affordable Care Act
- **PPS** - Prospective Payment System
- **PQRI** - Physician Quality Reporting Initiative
- **PRA** - Paperwork Reduction Act
- **PSO** - Patient Safety Organization
- **PT** - Physical Therapy
- **RAC** - Recovery Audit Contractor
- **RBRVS** - Resource-Based Relative Value Scale
- **Reconciliation Act** - Health Care and Education Reconciliation Act of 2010
- **REMS** - Risk Evaluation and Mitigation Strategy
- **RHQDAPU** - Reporting Hospital Quality Data for Annual Payment Update
- **RUG** - Resource Utilization Group
- **RVU** - Relative Value Units
- **RY** – Rate Year
- **SAMHSA** - Substance Abuse and Mental Health Services Administration
- **SNF** - Skilled Nursing Facility
- **SLP** - Speech Language Pathologist
- **SSA** - Social Security Act
- **SSDI** - Social Security Disability Insurance
- **STRIVE** - Staff Time and Resource Intensity Verification
- **VA** - Department of Veterans Affairs
- **VBP** - Value-Based Purchasing
- **WAC** – Wholesale Acquisition Cost